LAMPIRAN

ASUHAN KEBIDANAN TERHADAP SASARAN KIA/KB

(Remaja/ibu hamil/ibu bersalin/ibu nifas/bayi baru lahir/bayi/balita/PUS/klimakterium/menopause)

A. Pengkajian Data Subyektif

1. Identitas

Nama klien	: Ny. N	Nama suami	: Tn. ZS
Umur	: 33 th	Umur	: 33 th
Suku	: Jawa	Suku	: Jawa
Agama	: Islam	Agama	: Islam
Pendidikan	: SMU	Pendidikan	: D3
Pekerjaan	: Wiraswasta	Pekerjaan	: Ibu Rumah Tangga
Alamat	: Luwung Buntu RT 01/RW 02, Tamansari, Butuh, Purworejo		
Keluhan	: Ibu mengatakan mudah lelah		

2. Riwayat obstetrik dan ginekologi

Hamil Ke	Persalinan							Nifas	
	Tahun	Umur kehamilan	Jenis Persalinan	Penolong	Komplikasi	JK	BB Lahir	Laktasi	Komplikasi
1	Hamil ini								

3. Riwayat Menstruasi

HPHT / HPL : 19 Mei 2023 dan HPL 26 Februari 2024

Umur kehamilan 29 mg 6 hari

Lamanya : 7 hari
Banyaknya : 3 kali ganti pembalut/hari
Konsistensi : Cair dan ada gumpalan darah
Siklus : 28 hari
Menarche : 14 tahun
Teratur / tidak : Teratur
Dismenorrhea : Tidak
Keluhan lain : Tidak ada

4. Flour Albus

Banyaknya : Sedikit saja

Warna : Putih bening

Bau/gatal :Tidak bau/ Tidak gatal

5. Tanda-Tanda Kehamilan

Ibu mengatakan melakukan test kehamilan pada bulan Juli 2023 dengan hasil positif. Ibu merasakan gerakan janin pertama kali pada usia kehamilan 4 bulan. Dan ibu merasakan gerakan janin aktif kurang lebih 10 kali dalam 24 jam.

6. Riwayat Penyakit/Gangguan Reproduksi

Ibu mengatakan tidak memiliki penyakit reproduksi

7. Riwayat Imunisasi

Imunisasi TT : TT 3x

8. Riwayat Kesehatan

Ibu mengatakan keadaannya sangat baik.

9. Riwayat penyakit yang pernah dialami

Ibu mengatakan tidak menderita penyakit seperti hipertensi, jantung hepar, DM, PMS/HIV/AIDS, TBC. Ibu tidak mempunyai riwayat Operasi.

10. Riwayat Kesehatan Keluarga

Keluarga ibu dan suami tidak ada yang menderita penyakit seperti

Hipertensi, DM, TBC, Hepatitis, HIV/AIDS, serta penyakit keturunan seperti buta warna dan penyakit kelainan darah.

11. Riwayat Alergi

    Ibu mengatakan tidak memiliki riwayat alergi terhadap makanan dan obat-obatan.

12. Keluhan selama hamil

    Kurang istirahat karena banyaknya acara keluarga yang harus dihadiri.

13. Riwayat menyusui

    Ibu mengatakan belum pernah menyusui.

14. Riwayat KB

    Ibu mengatakan belum pernah menggunakan KB.

15. Kebiasaan Sehari-hari merokok dan penggunaan alkohol sebelum / selama hamil

    Ibu tidak memiliki kebiasaan merokok atau meminum alkohol baik sebelum atau selama hamil.

16. Obat- obatan atau jamu sebelum / selama hamil

    Selama hamil ibu tak mengonsumsi jamu-jamuan dan obat-obatan.

17. Pola makan atau diet

    Makan atau diet ibu selama hamil yaitu sehari 3-4 kali porsi sedang dan dihabiskan yaitu satu piring tidak penuh dengan takaran nasi 1 centong, lauk pauk seperti ikan, ayam, telur, tempe, sayur, dan kadang buah- buahan. Ibu baru bisa makan enak tanpa mual setlah umur kehamilan 16minggu. Sebelumnya mual muntah.

18. Pola Eliminasi

BAB		BAK	
Frekuensi	: 1x/ hari	Frekuensi	: >6 x/hari
Konsistensi	: Lunak	Konsistensi	: Cair
Warna	: Kuning kecoklatan	Warna	: Kuning jernih

Keluhan : Tidak ada Keluhan : Tidak ada

19. Pola istirahat dan tidur

    Siang : hampir tidak pernah

    Malam : ± 6 jam

20. Pola aktivitas sehari – hari

    Selama hamil, ibu sering beraktivitas di dalam rumah seperti memasak, menyapu, mencuci dan dan pekerjaan rumah lainnya. Diluar rumah.Ibu mengatakan sering jalan ke suatu tempat untuk rekreasi bersama dengan keluarga kerumah saudara.

21. Pola seksualitas

    Frekuensi : Tidak menentu

    Keluhan : Tidak ada

22. Riwayat Psikososial

    a. Pernikahan

       Status : Menikah satu kali

       Lamanya : 2 tahun

       Usia pertama kali menikah : 30 tahun

    b. Tingkat Pengetahuan Ibu terhadap Kehamilannya

       Cukup, ibu memahami pentingnya memeriksakan kehamilannya kepada tenaga kesehatan namun ibu kurang memahami mengenai HB yang rendah.

    c. Respon ibu terhadap kehamilannya

       Ibu merasa senang dengan kehamilannya saat ini.

    d. Harapan ibu terhadap jenis kelamin anak

       Ibu mengatakan perempuan atau laki-laki sama saja.

    e. Respon suami/keluarga terhadap jenis kelamin anak.

       Sangat senang, suami mengatakan anak perempuan atau laki – lakisama saja.

    f. Keperayaan yang berhubungan dengan kehamilan

       Ibu tidak ada suatu kepercayaan yang berhubungan dengan

kehamilan.

g. Pantangan selama kehamilan: Tidak Ada

h. Persiapan persalinan

Rencana tempat bersalin : Puskesmas Sruwohrejo

Persiapan ibu dan bayi : Ibu sudah mulai mempersiapkan biayapersalinan

B. Pengkajian Data Obyektif

1. Pemeriksaan Umum

Keadaan umum : baik

Kesadaran : composmentis

BB sebelum/ sesudah hamil : 48 kg/ 58 kg

TB : 155 cm

IMT sebelum/ sesudah hamil : 20/ 24,1

LILA : 24 cm

2. Tanda-Tanda Vital

TD : 110/65 mmhg

Pernafasan : 18 x/mnt

Nadi : 78 x/mnt

Suhu : 36,6^{0}C

3. Pemeriksaan Head to Toe

Kepala : Mesocephal, rambut bersih

Leher : Tidak ada pembesaran vena jugularis,tidak ada pembesaran kelenjar

Jantung : Denyut jantung teratur,ntidak terdengarmurmur

Paru-paru : Nafas normal,tidak ada sesak nafas, wheezing

Payudara : Simetris ,membesar,putting susu menojol, areola kehitaman

4. Abdomen

Leopold 1 : TFU : 21 cm,teraba lunak/bokong

Leopold 2 : Puka

Leopold 3 : Preskep

Leopold 4 : bagian terbawah janin belum masuk panggul

DJJ : 148x/mnt

Ekstremitas: Tidak oedema

5. Pemeriksaan Laboratorium tanggal 23-09-2023

HB	; 9,5 gr%	GDS	: 100 gr/dl
Protein urin	: Negatife (-)	Rapidtest HIV	: NR
Rapidtest HBSAg	: Neg	Rapidtest Siphilis	: Neg

Pemeriksaan HB ulang tanggal 12-12-2023 dengan hasil 10,0 gr%

6. Pemeriksaan lainnya : tidak ada
7. Analisa
   a. Diagnosa Kebidanan : Ny. N umur 33 tahun G1P0A0 Usia Kehamilan 29 mg 6 hari dengan kehamilan resiko anemia ringan dan perilaku suami yang suka merokok.
   b. Diagnosa Potensial :
      1) Terjadinya anemia sedang dan berat apabila tidak segera tertangani dengan baik.
      2) Terjadinya asma serta bali baru lahir rendah apabila tidak di cegah dari sekarang.
   c. Antisipasi Tindakan Segera
      1) Kolaborasi dengan petugas Gizi pemberian paket tambah darah dan asam folat, Vit C dan kalsium.
      2) Pendekatan dengan suami mengenai perilaku yang berakibat pada kehamilan istri serta pengaruh janinnya itu sendiri.
   d. Kebutuhan
      1) KIE tentang Kehamilan resiko tinggi, Gizi bumil Anemia dan pemberian TT 3 ibu hamil, pemberian tambah darah, asam folat dan Kalsium dan pemberian PMT bumil berupa biscuit ibu hamil 1 dus untuk 1 bulan.

2) KIE mengenai dampak dari paparan asap rokok yang dapat mengakibatkan asma pada perokok pasif, dan dapat pula mempengaruhi kondisi janin yaitu berat bayi baru lahir rendah jika perilaku tersebut di lakukan setiap hari dan berulang ulang di dekat istrinya yang sedang hamil.

8. Penatalaksanaan

a. Memberitahukan kepada ibu dan suami hasil dari pemeriksaan bahwa ibu termasuk kehamilan dengan resiko tinggi.

   Ny. N telah mengetahui hasil pemeriksaan dan Ny. N menyadari kalau dirinya beresiko tinggi dalam kehamilan dan akan mematuhi saran dari petugas.

b. Memberikan KIE dan konseling tentang kehamilan risiko tinggi faktor resiko dan resiko tinggi yang mungkin terjadi bagi si ibu dan janin selama kehamilan, persalinan dan nifas baik dampak bagi dirinya maupun bayinya.

   Ny N sudah mengerti tentang kehamilannya beresiko tinggi dan faktor kehamilan resiko tingginya,dan bagaimana cara / sikapnya dalam menghadapi kehamilannya ini dan akan memantapkan P4Knya baik selama kehamilan maupun pascasalinnya.

c. Memberikan KIE dan konseling kepada ibu dan suami mengenai paparan asap rokok terhadap kehamilan ibu dan yang mungkin terjadi bagi si bayi selama kehamilan, yaitu akan berdampak pada asma serta bagi bayi dapat mengakibatkan bayi baru lahir rendah karena paparan asap rokok yang di hirup ibu selama masa hamilnya.

   Ibu dan suami paham dengan penjelasan yang di berikan dan suami berjanji jika dirinya merokok akan di luar rumahdan tidak berada di dekat istrinya. Suami juga berjanji sedikit demi sedikit akan mengurangi frekuensi merokoknya.

d. Menganjurkan kepada suami/ keluarga untuk mendukung baik moril maupun tenaga guna membantu Ny. N untuk mengurangi

aktifitas sehari-hari agar bisa beristirahat cukup guna memperbaiki kondisi kesehatannya yang beresiko agar lebih baik.

Suami / Keluarga Ny. N bersedia memberikan dukungan moril maupun tenaga dalam membantu mengurus rumah tangga.

e. Kolaborasi petugas kesehatan lain yaitu pemeriksaan darah di laboratorium dan konsultasi gizi.

Berdasarkan hasil pemeriksaan darah di laboratorium Ny. N mengalami Anemia yaitu HB 10 gr% dan konsultasi gizi dengan diet bumil anemia.

f. Kolaborasi dengan petugas gizi

Disarankan mengonsumsi makanan bernutrisi dan bergizi tinggi, khususnya yang kaya zat besi dan asam folat setiap hari seperti daging (sapi atau unggas) rendah lemak yang dimasak matang makanan laut seperti ikan, cumi, kerang, dan udang yang dimasak matang telur yang dimasak matang sayuran hijau, misalnya bayam dan kangkung, kacang polong, produk susu yang telah dipasteurisasi, kentan dan gandum.

Ny. N sudah mengerti tentang makanan apa saja yang kayaakan zat besi dan asam folat dan akan dipraktekkan dalam komposisi makannya.

g. Pemberian imunisasi TT 3 dan paket tablet tambah darah dan asam folat dan kalsium.

Ny. N belum di TT 3 dan sudah menerima obat yang diresepkan petugas dan akan meminum obat yang diberikan tablet tambah darah 30 tablet (1 Paket) Asam folat , kalsium dan Vit C sesuai anjuran sehari 1 tablet.

h. Menganjurkan untuk datang kembali jika obat habis /bila ada keluhan/ tanda bahaya trimester III.

Ny. N akan kembali kontrol jika obat yang diberikan sudah habis dan jika ada keluhan.

i. Memotivasi suami dan anggota keluarga yang lain untuk

mendukung ibu dan ikut memantau kepatuhan ibu minum obat tablet tambah darah setiap hari,serta mendukung ibu untuk makan makananbergizi.

Ibu berjanji akan meminum obat dan vitaminnya secara rutin.

j. Melakukan dokumentasi.

Dokumentasi telah dilakukan.

9. Evaluasi

a. Menjelaskan hasil pemeriksaan pada pasien bahwa pemeriksaan tanda vital normal. Pada pemeriksaan laboratorium tgl 12-12-2022, kadar Hb: 10,0 gr/dl. Dalam hal ini pasien mengalami masuk ke dalam kategori anemia ringan.

Pasien mengerti dengan penjelasan yang diberikan.

b. Menjelaskan tentang keluhan nyeri punggungnya merupakan hal yang wajar karena semakin besarnya janin akan membuat beban tulang punggung dalam menopang tubuh semakin berat. Cara untuk mengurangi adalah dengan memperbaiki postur tubuh dengan berdiri atau duduk tegak dan regangkan punggung secara berkala untuk menghindari nyeri. Melakukan pemijatan pada daerah punggung. Menggunakan penyangga perut atau korset untuk ibu hamil juga dapat membantu mengurangi nyeri punggung saat hamil.

Pasien mengerti dengan penjelasan yang diberikan dan akan melaksanakan anjuran yang diberikan untuk mengurangi nyeri punggung yang dirasakan.

Menjelaskan tentang keluhan nyeri punggungnya merupakan hal yang wajar karena semakin besarnya janin akan membuat beban tulang punggung dalam menopang tubuh semakin berat. Cara untuk mengurangi adalah dengan memperbaiki postur tubuh dengan berdiri atau duduk tegak dan regangkan punggung secara berkala untuk menghindari nyeri. Melakukan pemijatan pada daerah punggung. Menggunakan penyangga perut atau korset untuk ibu

hamil juga dapat membantu mengurangi nyeri punggung saat hamil.

Pasien mengerti dengan penjelasan yang diberikan dan akan melaksanakan anjuran yang diberikan untuk mengurangi nyeri punggung yang dirasakan.

c. Menjelaskan pada ibu bahwa anemia lebih banyak terjadi di trimester ketiga. Peningkatan trimester dapat menyebabkan penurunan cadangan besi pada ibu. Oleh sebab itu ibu harus rutin minum obat tablet tambah darah agar Hb tidak mengalami penurunan.

   Ibu paham dengan penjelasan yang di berikan.

d. Memberikan KIE dan konseling kepada ibu dan suami mengenai paparan asap rokok terhadap kehamilan ibu dan yang mungkin terjadi bagi ibu mapun si bayi selama kehamilan, yaitu akan berdampak pada asma serta pada bayi dapat mengakibatkan bayi baru lahir rendah karena paparan asap rokok yang di hirup ibu selama masa hamilnya.

   Ibu dan suami paham dengan penjelasan yang di berikan.

e. Memberikan edukasi tanda bahaya kehamilan trimester 3, yaitu gerakan janin berkurang dari biasanya minimal 10 gerakan dalam 12 jam tiap hari, perdarahan dari jalan lahir, demam tinggi, kaki bengkak dan sakit kepala disertai kejang.

   Pasien mengerti dan mampu mengulangi penjelasan yang diberikan.

f. Memberikan edukasi bahwa bahwa pasien harus banyak mengkonsumsi makanan yang mengandung protein hewani dan memperbanyak sayuran hijau untuk meningkatkan Hb ibu hamil. Serta mengurangi untuk mengkonsumsi teh dan kopi.

   Ibu mengerti penjelasan yang diberikan.

g. Menganjurkan ibu untuk melakukan swab antigen di Puskesmas pada usia kehamilan 37-38 minggu atau sebelum ibu mendekati HPL.

Ibu bersedia untuk swab antigen.

h. Memberikan terapi tablet tambah darah SF 30 mg 2x1 dan kalsium 500mg 1x1 dan asam folat 1x 400mg.
   Ibu bersedia meminum terapi yang diberikan sesuai aturan.

i. Menganjurkan pada pasien jika merasa mual ketika minum tablet tambah darah di sarankan untuk mengkonsumsi di malam hari sebelumtidur atau mengkonsumsi dengan air jeruk atau jus buah.
   Ibu mengerti dengan penjelasan yang di berikan dan akan dicoba sesuai saran.

j. Menganjurkan pada ibu untuk kunjungan ulang 4 minggu lagi.
   Ibu bersedia untuk kontrol ulang 4 minggu lagi.

k. Memberikan konseling kepada ibu jika nanti diumur kehamilan 36 minggu, pasien dianjurkan untuk melakukan ANC terpadu ke 2 untuk dilakukan pemeriksaan lab lengkap seperti HB, Protein Urine, HIV, HbSAG, Sifilis.
   Ibu mengerti dengan penjelasan yang diberikan dan akan melaksanakansesuai anjuran

l. Menganjurkan ibu untuk melakukan USG atau kontrol kepada dokterspesialis sebelum HPL untuk memastikan kesehatan janin.
   Ibu mengerti dengan penjelasan yang diberikan.

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU HAMIL KUNJUNGAN ULANG NY. N UMUR 33 TAHUN G1P0A0 UK 35 MINGGU HAMIL NORMAL DI PUSKESMAS SRUWOHREJO KABUPATEN PURWOREJO

TANGGAL/JAM : 18 Januari 2024 / 09.00 WIB

Biodata Ibu		Biodata Suami	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengatakan ingin melakukan pemeriksaan ulang kehamilan. Ibu mengatakan ini kehamilan yang pertama. Ibu mengeluh sering sesak. Riwayat menstruasi: HPHT: 19/5/2022, siklus: ± 28 hari, lamanya 5-7 hari Riwayat pernikahan: menikah 1x, lamanya 1 tahun. Riwayat penyakit ibu: ibu tidak mempunyai riwayat penyakit hipertensi, DM, asama dan TBC. Riwayat penyakit keluarga: keluarga tidak memiliki riwayat penyakit hipertensi, DM, asma dan TBC. Status imunisasi TT3 Pola aktivitas sehari-hari: ibu selain menjadi ibu rumah tangga. Pola pemenuhan nutrisi makan 3x sehari, minum ± 8 gelas/ hari.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 114/80 mmHg, suhu

36^{o}C, nadi 85x/menit, RR 20x/menit, TB 155 cm, BB 60 kg, TFU 24 cm, punggung kanan, presentasi kepala, DJJ 131x/menit. Lila 25 cm, HB 10,2 gr/dl, protein urine (-), ekstremitas tidak odema, TBJ (24-11)x155=2015 gram.

A : Ny. N umur 33 tahun G1P0A0 usia kehamilan 35 minggu janin hidup, intrauteri, letak memanjang, punggung kanan, presentasi kepala, sudah masuk masuk panggul, normal.

P :

1. Memberitahu Ibu mengenai hasil pemeriksaan bahwa kondisi Ibu dan janin saat ini baik dan sehat.

   (Ibu mengerti dan merasa senang)

2. Melakukan kolaborasi dengan dokter di BPU mengenai sesak yang ibu keluhkan.

   (Dokter mengatakan kepada ibu tidak perlu merasa cemas. Sesak yang dialami ibu bisa terjadi karena tekanan karena janin semakin besar).

3. Memberi tahu ibu cara mengatasi sesak yaitu pada saat berbaring, ibu disarankan untuk setengah duduk, atau dapat miring ke kiri atau kanan. Ibu tidak disarankan berbaring dalam posisi terlentang.

   (Ibu mengerti).

4. Memberikan ibu obat tablet tambah darah 1x1 (10 tablet) dan kalsium laktat1x1 (10 tablet)

   (Ibu mengerti dan berjanji akan meminumnya).

5. Menganjurkan ibu untuk mempersiapkan semua yang dibutuhkan untuk persalinan dalam 1 tas (seperti persyaratan BPJS, peralatan bayi, dan ibu).

(Ibu mengerti).

6. Menganjurkan ibu untuk kunjungan ulang 1 minggu yang akan datang, atau terdapat tanda bahaya trimester III, seperti perdarahan, keluar air ketuban, nyeri ulu hati, pandangan kabur. Atau jika terdapat tanda-tanda persalinan seperti kontraksi 2-3 x dalam 10 menit dan teratur, keluar lendir darah.

   (Ibu mengerti).

7. Mendokumentasikan asuhan yang telah diberikan.

   (Dokumentasi telah dilakukan di register, kohort, rekam medik, serta buku KIA ibu).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU HAMIL KUNJUNGAN ULANG NY. N UMUR 33 TAHUN G1P0A0 UK 39 MINGGU 1 HARI HAMIL NORMAL DI PUSKESMAS SRUWOHREJO KABUPATEN PURWOREJO

TANGGAL/JAM : 15 Februari 2024 / 10.00 WIB

Biodata Ibu		Biodata Suami	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengatakan ingin melakukan pemeriksaan ulang kehamilan. Ibu sesekali merasakan kenceng- kenceng tapi tidak sering.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 104/75 mmHg, suhu 36.7^{o}C, nadi 80x/menit, RR 20x/menit, TB 155 cm, BB 62 kg, Lila 25 cm, Hb 11,2 gr/dl, protein urine (-), ekstremitas tidak odema, TFU 29 cm, punggung kanan, presentasi kepala, DJJ 143x/menit, TBJ (29-11)x155 = 2790 gram.

A : Ny. N umur 33 tahun G1P0A0 usia kehamilan 39 minggu 1 hari janin hidup, intrauteri, letak memanjang, punggung kanan, presentasi kepala, sudah masuk masuk panggul, normal.

P :

1. Memberitahu Ibu mengenai hasil pemeriksaan bahwa kondisi Ibu dan janin

saat ini baik dan sehat.
(Ibu mengerti dan merasa senang)

2. Memberi tahu ibu tanda-tanda persalinan, yaitu kontraksi 2-3 kali dalam 10menit dan teratur, keluar lendir darah dari jalan lahir.

   (Ibu mengerti)

3. Memberi tahu ibu tanda bahaya trimester III, antara lain perdarahan, keluar air ketuban, nyeri ulu hati, pusing, pandangan kabur.

   (Ibu mengerti)

4. Menganjurkan ibu untuk mempersiapkan semua yang dibutuhkan untuk persalinan dalam 1 tas (seperti persyaratan BPJS, peralatan bayi, dan ibu)
   (Ibu mengatakan telah mempersiapkannya dalam 1 tas)

5. Memberikan ibu obat tablet tambah darah 1x1 (7 tablet) dan kalsium laktat 1x1 (7 tablet).

   (Ibu mengerti dan akan meminumnya)

6. Menganjurkan ibu untuk kunjungan ulang 1 minggu yang akan datang, atau terdapat tanda bahaya trimester III, atau jika terdapat tanda-tanda persalinan.

   (Ibu mengerti)

7. Mendokumentasikan asuhan yang telah diberikan.

   (Dokumentasi telah dilakukan di register, kohort, rekam medik, serta buku KIA ibu)

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU HAMIL KUNJUNGAN ULANG NY. N UMUR 33 TAHUN G1P0A0 UK 40 MINGGU 1 HARI DENGAN KETUBAN PECAH DINI DI PUSKESMAS SRUWOHREJO KABUPATEN PURWOREJO

TANGGAL/JAM : 28 Februari 2024 / 12.45 WIB

Biodata Ibu		Biodata Suami	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu datang ke Puskesmas Sruwohrejo Purworejo dengan keluar air dari jalan lahir sejak pukul 10.00 WIB, dan kenceng belum sering.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 107/78 mmHg, suhu 36.5^{o}C, nadi 88x/menit, RR 20x/menit, TB 155 cm, BB 62 kg, Lila 25 cm, Hb terakhir 11,4 gr/dl, protein urine (-), ekstremitas tidak odema, TFU 29 cm, punggung kanan, presentasi kepala, DJJ 143x/menit, TBJ (29-11)x155 = 2790 gram. Dilakukan Pemeriksaan pukul 13.00 WIB : V/U tenang, dinding vagina licin, portio tebal, Ø 1 cm, presentasi kepala, kepala turun HIII, air ketuban (+), STLD (-), HIS 1x10’10.

A : Ny.N umur 33 tahun G1P0A0 usia kehamilan 40 minggu 1 hari, janin tunggal hidup, intrauteri, dengan KPD.

P :

1. Menjelaskan kepada ibu dan keluarga tentang keadaan ibu dan bayinya.
   (Ibu dan keluarga mengerti dengan keadaannya sekarang)
2. Meminta ibu untuk Bedrest, dan tidak jalan- jalan karena air ketuban sudah rembes
   (Ibu mengerti dengan penjelasan yang di berikan)
3. Memberikan ibu antibiotik amoxicilin 500 mg atas advice dokter untuk diminum ibu, karena sudah KPD
   (Ibu meminum obat tersebut)
4. Melakukan observasi kepada ibu dan akan di VT ulang 4 jam lagi (Selama observasi ibu miring ke kiri sesekali telentang, dan tetap makan minum, sembari relaksasi serta atur nafas ketika kontrasi muncul)

CATATAN PERKEMBANGAN

Pukul : 17.00 WIB

S	O	A	P
Ibu mengatakan masih keluar air dari jalan lahir	**VT ke -2** TD : 108/78 mmhg, S: 36.6^{0}C N : 86 x/menit R : 22 x/menit v/u tenang, dinding vagina licin, porsio tebal, pembukaan Ø 2 cm, selaput ketuban (+), preskep, kepala hodge III, AK (+) jernih, STLD (-), HIS1x10'20", DJJ :134x/m	Ny.RR umur33 tahun G1P0A0Ah0 usia kehamilan 40 minggu 1 hari, janin tunggal hidup, dengan KPD	- Meminta ibu tetap makan minum - Mengingatkan ibu untuk tidak menahan BAB dan BAK - Memberikan kenyamanan terhadap mobilisasi ibu - Melanjutkan untuk observasi ibu

CATATAN PERKEMBANGAN

Pukul 21.00 WIB

S	O	A	P
Ibu mengatakan masih keluarair dari jalan lahir, dan kenceng bertambah	**VT ke -3** TD : 110/80 mmhg, S: 36.6^{0}C N : 84 x/menit R : 20 x/menit v/u tenang, dinding vagina licin, porsio tebal, pembukaan Ø 2 cm, selaput ketuban (+), preskep, kepala hodge III, AK (+) jernih, STLD (-), HIS 2x10'25" DJJ :136x/m	Ny.RR umur33 tahun G1P0A0Ah0 usia kehamilan 40 minggu 1 hari, janin tunggal hidup, dengan KPD sudah 11 jam	- Konsul dokter karena tidak ada penambah pembukaan, dan kenceng belum terlalu sering - Adv dokter Pusk : Rujuk RS. Tjotrowardoyo, karena air ketuban sudah rembes 11 jam - Memberikan dukungan emosional dan spiritual terhadap ibu dan keluarga - Meyakinkan dan memberikan semangat terhadap ibu dan keluarga. - Memberitahu ibu dan keluarga bahwa akan di lakukan perujukan ke RS agar segera tertangani dan mendapat tindakan.

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU BERSALIN NY. N UMUR 33 TAHUN G1P0A0 UK 40 MINGGU 2 HARI SC DENGAN KETUBAN PECAH DINI 12 JAM DI RSUD TJITROWARDOYO KABUPATEN PURWOREJO

TANGGAL/JAM : 28 Februari 2024 / 22.00 WIB

Biodata Ibu		Biodata Suami	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu datang ke IGD RSUD Tjitrowardoyo Purworejo dengan diantar bidan dari Puskesmas dan surat rujukan dari Puskesmas Sruwohrejo dengan diagnosa ketuban pecah dini 12 jam . Ibu mengatakan terasa mules atau kencang-kencang, dan ada keluar lendir darah. Dari rujukan Puskesmas Sruwohrejo terdapat indikasi rujukan yaituketuban pecah dini selama 12 jam yang sebelum nya ibu sudah di observasi selama 8 jam di Puskesmas. Sesampai di RSUD Tjitrowardoyo setelah dilakukan pemeriksaan advice dokter SPOG langsung masuk rawat inap untuk dilakukan persiapan operasi. Operasi dijadwalkan pukul 08.00 WIB. Ibu diminta puasa sejak direncanakan SC.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 108/70 mmHg, suhu 36.5^{o}C, nadi 80x/menit, RR 20x/menit, TB 155 cm, BB 62 kg, Lila 25 cm, Hb terakhir 11,4 gr/dl, protein urine (-), ekstremitas tidak odema, kertas lakmus berubah warna menjadi biru, TFU 29 cm, punggung kanan, presentasi kepala, DJJ 144x/menit, TBJ (29-11)x155 = 2790 gram.

A : Ny.N umur 33 tahun G1P0A0 usia kehamilan 40 minggu 2 hari, janintunggal hidup, intrauteri, rencana SC.

P :

1. Menjelaskan kepada ibu dan keluarga tentang prosedur tindakan yang akan dilakukan dan meminta persetujuan tindakan.
2. Melakukan persiapan operasi, seperti meminta ibu untuk puasa sejak pukul 00.00 WIB, melakukan pemasangan infus dan kateter, serta pemberian antibiotik secara IV.
3. Mengantar ibu ke ruang operasi.
4. Melakukan resusitasi sampai tahap awal, dan pemeriksaan antropometri serta tanda-tanda vital. (Resusitasi telah dilakukan bayi menangis kuat. BBL: 2930 gram, PB 49 cm,jenis kelamin laki-laki. HR : 144x/menit, RR: 48 x/menit, S: 36.5^{o}C).
5. Melakukan pemberian salep mata dan injeksi vitamin K1 1 mg di paha kiri atas bayi. (Salep mata dan vitamin K1 telah diberikan).
6. Memberikan bayi kepada ibu untuk dilakukan IMD. (IMD telah dilakukan kurang lebih 30 menit).
7. Melakukan observasi pasca operasi selama 2 jam. (Selama observasi keadaan umum ibu baik, dan tidak terjadi perdarahan. Ibu dipindahkan ke ruang nifas).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU KB IUD POST PARTUM PADA NY. N UMUR 33 TAHUN P1A0 DI RSUD TJITROWARDOYO KABUPATEN PURWOREJO

TANGGAL/JAM : 1 Maret 2024 / 09.30 WIB

Biodata Ibu		Biodata Suami	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengatakan ingin KB IUD postpartum dan sudah menandatangani inform consent.

O : Keadaan umum ibu baik, kesadaran composmentis, TD : 110/70 mmhg, S: 36.5^{0}C, N : 80 x/menit, R : 20 x/menit, TB 155 cm, Lila 25 cm, Hb 11,4 gr/dl.

A : Ny. N umur 33 tahun P1A0 dengan KB IUD post partum.

P :

1. Menjelaskan kepada ibu dan keluarga tentang prosedur tindakan yang akandilakukan dan meminta persetujuan ulang. (Ibu dan keluarga mengerti dan telah menandatangani informed consent).
2. Memberi tahu ibu manfaat, efek samping yang di timbulkan. (Ibu paham dengan penjelasan yang diberikan).
3. Memberitahu ibu untuk kontrol ulang 7 hari. (Ibu paham dengan penjelasan yang diberikan).

4. Memberitahu ibu bahwa KB IUD berlaku 5 tahun semenjak tanggal pemasangan, namun dapat di lepas sewaktu waktu tidak harus menunggu sampai 5 tahu, dan harus kontrol 1 tahun sekali. (Ibu paham atas apa yang di jelaskan).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA BAYI BARU LAHIR PADA BAYI NY. N UMUR 0 JAM BAYI DI RSUD TJITROWARDOYO KABUPATEN PURWOREJO

TANGGAL/JAM : 1 Maret 2024 / 08.40 WIB

Biodata Ibu		Biodata Ayah	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Bayi lahir dari ibu G1P0A0 UK 40 minggu 3 hari secara SC atas indikasi ketuban pecah dini. Bayi langsung menangis.

O : Keadaan umum bayi baik, kesadaran composmentis, S 36,5^{o}C, Nadi 144x/menit, RR 48x/menit, jenis kelamin laki-laki, BAB (-), BAK (+), PB 49 cm, BB 2930 gram, LK 32 cm, LD 33 cm.

A : By Ny. N umur 0 jam bayi lebih bulan sesuai masa kehamilan SC atas indikasi ketuban pecah dini.

P :

1. Melakukan asuhan bayi baru lahir, mengeringkan, menghangatkan bayi, pemeriksaan dasar bayi baru lahir. (Asuhan bayi baru lahir di lakukan).
2. Melakukan pemberian salep mata dan injeksi vitamin K1 1 mg di paha kiri atas bayi. (Salep mata dan vitamin K1 telah diberikan).
3. Memberi tahu ibu bayi dalam keadaan sehat. (Ibu merasa senang).

4. Meletakkan bayi di atas perut ibu untuk dilakukan IMD (IMD sudah dilakukan kurang lebih 30 menit).
5. Membawa bayi ke ruang perinatologi untuk diobservasi, jika keadaan bayi baik maka akan dilakukan rawat gabung. (Selama observasi keadaan bayi baik, bayi dapat diberikan ke ibu untuk rawat gabung).
6. Memberikan imunisasi Hb 0 di paha kanan bayi secara IM setelah 6 jam. (Imunisasi telah diberikan).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU NIFAS PADA NY. N UMUR 33 TAHUN P1A0 POST SC 1 HARI DI RSUD TJITROWARDOYO KABUPATEN PURWOREJO

TANGGAL/JAM : 2 Maret 2024 / 10.00 WIB

Biodata Ibu		Biodata Ayah	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengeluh nyeri luka operasi, perut terasa mules, dan ASI belum banyak.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 108/72 mmHg, S 36^{o}C, RR 18x/menit, N 80x/menit, TFU 2 jari dibawah pusat, perdarahan normal, lochea rubra, ASi (+), BAK (+), BAB (-).

A : Ny. N umur 33 tahun P1A0 Post SC 1 hari atas indikasi ketuban pecah dini.

P :

1. Memberi tahu ibu keadaan ibu baik. (Ibu mengerti).
2. Memberi tahu ibu nyeri pada luka operasi lebih terasa karena pengaruh anastesi sudah hilang, sehingga nanti ibu akan diberikan antinyeri secara oral. (Ibu mengerti).
3. Memberi tahu ibu mules yang dirasakan adalah hal yang normal, terjadi karena rahim berkontraksi untuk kembali ke ukuran sebelum hamil. (Ibu mengerti).

4. Meminta ibu untuk melakukan mobilisasi bertahap, seperti miring ke kiri dan ke kanan, dan mulai belajar duduk. (Ibu sudah belajar miring kiri, kanan, dan duduk).
5. Menganjurkan ibu untuk memberikan ASI secara eksklusif dan on demand. (Ibu mengerti).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA BAYI BARU LAHIR PADA BAYI NY. N UMUR 1 HARI BAYI DI RSUD TJITROWARDOYO KABUPATEN PURWOREJO

TANGGAL/JAM : 2 Maret 2024 / 08.40 WIB

S : Bayi Ny. N sudah bisa menyusu.

O ; Keadaan umum bayi baik, kesadaran composmentis, S 36.9^{o}C, nadi 144 x/menit, RR 58 x/menit, jenis kelamin laki-laki, BAB (+), BAK (+), tali pusat masih basah.

A : By. Ny. N umur 1 hari bayi lebih bulan sesuai masa kehamilan SC atas indikasi ketuban pecah dini.

P :

1. Memberi tahu ibu keadaan bayi baik.
   (Ibu merasa senang).
2. Memberi tahu ibu dan keluarga untuk menjaga kehangatan dan kebersihan bayi, seperti segera mengganti popok bayi jika BAB atau BAK.
   (Ibu dan keluarga mengerti).
3. Menganjurkan ibu untuk memberikan ASI ekslusif on demand.
   (Ibu mengerti).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU NIFAS PADA NY. N UMUR 33 TAHUN P1A0 POST SC HARI KE-16

TANGGAL/JAM : 17 Maret 2024 / 14.00 WIB

Biodata Ibu		Biodata Ayah	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengatakan tidak ada keluhan, ASI lancer.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 110/70 mmHg, S 36,8^{o}C, RR 20x/menit, nadi 80x/menit, TFU tidak teraba, luka operasi kering, perdarahan normal, lochea serosa, ASI lancar, BAK (+), BAB (+).

A : Ny. N umur 33 tahun P1A0 Post SC hari ke 16.

P :

1. Memberi tahu ibu keadaan ibu baik, luka jahitan baik, kering, tidak ada tanda-tanda infeksi.
   (Ibu mengerti).
2. Memberi tahu ibu tanda bahaya pada masa nifas, diantaranya: demam, perdarahan dari jalan lahir yang berlebihan atau berbau.
   (Ibu mengerti).
3. Mengganti verban luka operasi.
   (Verban telah diganti).
4. Menganjurkan ibu untuk mengkonsumsi makanan tinggi protein, seperti putih telur, ikan gabus.

(Ibu mengerti).

5. Memotivasi ibu untuk memberikan ASI eksklusif sampai anak berusia 6 bulan.

   (Ibu mengerti dan akan berusaha untuk memberikan ASI eksklusif).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA BAYI BARU LAHIR PADA BAYI NY. N UMUR 16 HARI

TANGGAL/JAM : 17 Maret 2024 / 14.00 WIB

S : Ibu mengatakan bayinya tidak ada keluhan,

O : Keadaan umum baik, kesadaran composmentis, S 36,8^{o}C, nadi 140x/menit, RR 50x/menit, tali pusat sudah lepas tidak ada infeksi, ASI lancar.

A : By. Ny. N umur 16 hari normal.

P :

1. Memberi tahu ibu keadaan bayi baik.
   (Ibu merasa senang).
2. Memberi tahu ibu untuk tetap memberikan ASI eksklusif sampai usia 6 bulan.
   (Ibu mengerti).
3. Memberi tahu ibu untuk membawa bayi ke puskesmas terdekat untuk mendapat imunisasi sesuai dengan jadwal yang ada di buku KIA.
   (Ibu mengerti).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA IBU NIFAS PADA NY. N UMUR 33 TAHUN P1A0 POST SC HARI KE-30

TANGGAL/JAM : 31 Maret 2024 / 16.00 WIB

Biodata Ibu		Biodata Ayah	
Nama	: Ny. N	Nama	: Tn. Z
Umur	: 33 tahun	Umur	: 33tahun
Agama	: Islam	Agama	: Islam
Pendidikan	: SMA	Pendidikan	: D3
Pekerjaan	: IRT	Pekerjaan	: Wiraswasta
Alamat	: Sruwohrejo, Kecamatan Butuh, Kabupaten Purworejo		

S : Ibu mengatakan tidak ada keluhan, ASI lancer.

O : Keadaan umum ibu baik, kesadaran composmentis, TD 110/70 mmHg, S 36,8^{o}C, RR 20x/menit, nadi 80x/menit, TFU tidak teraba, luka operasi kering, perdarahan normal, lochea alba, ASI lancar, BAK (+), BAB (+).

A : Ny. N umur 33 tahun P1A0 Post SC hari ke 30.

P :

1. Memberi tahu ibu keadaan ibu baik, luka jahitan baik, kering, tidak ada tanda-tanda infeksi.
   (Ibu mengerti).
2. Mengajarkan ibu serba-serbi ASI perah, seperti cara memerah yang baik, cara penyimpanan dan pemberian ASI perah.
   (Ibu mengerti).
3. Menganjurkan ibu untuk mengkonsumsi makanan dengan gizi seimbang.
   (Ibu mengerti).
4. Memotivasi ibu untuk memberikan ASI eksklusif sampai anak berusia 6 bulan.

(Ibu mengerti dan akan berusaha untuk memberikan ASI eksklusif).

5. Memberi tahu ibu untuk datang kembali jika terdapat keluhan.
   (Ibu mengerti).

PRODI PENDIDIKAN PROFESI BIDAN

JURUSAN KEBIDANAN POLTEKKES KEMENKES YOGYAKARTA

Jalan Mangkuyudan MJ III/304 Yogyakarta 55143 Telp (0274) 374331

ASUHAN KEBIDANAN PADA BAYI BARU LAHIR PADA BAYI NY. N UMUR 30 HARI DENGAN IMUNISASI BCG

TANGGAL/JAM : 31 Maret 2024 / 09.00 WIB

S : Ibu datang ke puskesmas untuk memberikan imunisasi kepada bayinya. Ibu mengatakan bayinya tidak ada keluhan.

O : Keadaan umum baik, kesadaran composmentis, S 36,8^{o}C, nadi 142x/menit, RR 46x/menit, BB 3800 gram, PB 50 cm.

A : By. Ny. N umur 30 hari dengan imunisasi BCG.

P :

1. Memberi tahu ibu keadaan bayi baik, dan dapat diberikan imunisasi BCG.
   (Ibu mengerti dan merasa senang).
2. Memberi tahu ibu tentang manfaat imunisasi BCG, prosedur penyuntikannya, dan efek samping yang akan terjadi.
   (Ibu mengerti).
3. Meminta ibu untuk menandatangani infomed consent pemberian imunisasi BCG
   (Ibu telah menandatangani informed consent).
4. Memberikan suntikan BCG di lengan kanan bayi bagian atas secara intra cutan.
   (Bayi telah diberikan imunisasi BCG).
5. Memberi tahu ibu untuk datang kembali 1 bulan yang akan datang untuk mendapat imunisasi selanjutnya yaitu polio dan Pentabio I.
   (Ibu mengerti).

INFORMED CONSENT (SURAT PERSETUJUAN)

Yang bertanda tangan di bawah ini :

Nama : Nur Ngaeni

Tempat/Tanggal Lahir : Purworejo, 6 Agustus 1991

Alamat : Luwung Buntu RT 01/RW 02, Tamansari, Butuh, Purworejo

Bersama ini menyatakan kesediaan sebagai subjek dalam praktik Continuity of Care (COC) pada mahasiswa Prodi Pendidikan Profesi Bidan T.A. 2023/2024. Saya telah menerima penjelasan sebagai berikut :

1. Setiap tindakan yang dipilih bertujuan untuk memberikan asuhan kebidanan dalam rangka meningkatkan dan mempertahankan kesehatan fisik, mental ibu dan bayi. Namun demikian, setiap tindakan mempunyai risiko, baik yang telah diduga maupun yang tidak diduga sebelumnya.
2. Pemberi asuhan telah menjelaskan bahwa ia akan berusaha sebaik mungkin untuk melakukan asuhan kebidanan dan menghindarkan kemungkinan terjadinya risiko agar diperoleh hasil yang optimal.
3. Semua penjelasan tersebut di atas sudah saya pahami dan dijelaskan dengan kalimat yang jelas, sehingga saya mengerti arti asuhan dan tindakan yang diberikan kepada saya. Dengan demikian terdapat kesepahaman antara pasien dan pemberi asuhan untuk mencegah timbulnya masalah hukum di kemudian hari.

Demikian surat persetujuan ini saya buat tanpa paksaan dari pihak manapun dan agar dipergunakan sebagaimana mestinya.

Yogyakarta, 18 Januari 2024

Mahasiswa	Klien
(TRI JUNIKA KHOIRUNISSA)	(NUR NGAENI)

SURAT KETERANGAN

Yang bertanda tangan dibawah ini :

Nama Pembimbing Klinik : Evita Istriana, S.Tr.Keb.,Bdn
Instansi : Puskesmas Sruwohrejo Purworejo

Dengan ini menerangkan bahwa :

Nama Mahasiswa : Tri Junika Khoirunissa
NIM : P07124523004
Prodi : Pendidikan Profesi Bidan
Jurusan : Kebidanan Poltekkes Kemenkes Yogyakarta

Telah selesai melakukan asuhan kebidanan berkesinambungan dalam rangk apraktik kebidanan holistik *Continuity of Care* (COC) .
Asuhan dilaksanakan pada tanggal 18 Januari 2024 sampai dengan 30 Maret 2024.
Judul Asuhan : Asuhan Berkesinambungan pada Ny. N Umur 33 Tahun G1P0A0 dengan Ketuban Pecah Dini di Puskesmas Sruwohrejo Kabupaten Purworejo.

Demikian surat keterangan ini dibuat dengan sesungguhnya untuk dipergunakan sebagaimana mestinya.

Yogyakarta, 30 Maret 2024
Bidan (Pembimbing Klinik)

Evita Istriana, S.Tr.Keb.,Bdn


Viola

Cochrane Library

Cochrane Database of Systematic Reviews

Oral misoprostol for induction of labour (Review)

Alfirevic Z, Aflaifel N, Weeks A

Alfirevic Z, Aflaifel N, Weeks A.
Oral misoprostol for induction of labour.
Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD001338.
DOI: 10.1002/14651858.CD001338.pub3.

www.cochranelibrary.com

WILEY

Cochrane Library
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Cochrane Database of Systematic Reviews

[Intervention Review]

Oral misoprostol for induction of labour

Zarko Alfirevic[1], Nasreen Aflaifel[1], Andrew Weeks[1]

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ABSTRACT

Background

Misoprostol is an orally active prostaglandin. In most countries misoprostol is not licensed for labour induction, but its use is common because it is cheap and heat stable.

Objectives

To assess the use of oral misoprostol for labour induction in women with a viable fetus.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (17 January 2014).

Selection criteria

Randomised trials comparing oral misoprostol versus placebo or other methods, given to women with a viable fetus for labour induction.

Data collection and analysis

Two review authors independently assessed trial data, using centrally-designed data sheets.

Main results

Overall, there were 75 trials (13,793 women); these were of mixed quality.

In nine trials comparing oral misoprostol with placebo (1109 women), women using oral misoprostol were more likely to give birth vaginally within 24 hours (risk ratio (RR) 0.16, 95% confidence interval (CI) 0.05 to 0.49; one trial; 96 women) and less likely to undergo caesarean birth (RR 0.72, 95% CI 0.54 to 0.95; 8 trials; 1029 women). Differences in 'uterine hyperstimulation with fetal heart rate changes' were compatible with no effect (RR 2.71, 95% CI 0.84 to 8.68; 7 trials; 669 women).

Ten trials compared oral misoprostol with vaginal prostaglandin (dinoprostone) (3,240 women). There was little difference in the frequency of: vaginal birth within 24 hours (RR 1.10, 95% CI 0.99 to 1.22; 5 trials; 2,128 women), uterine hyperstimulation with fetal heart rate changes (RR 0.95, 95% CI 0.59 to 1.53; 7 trials; 2,352 women), and caesarean birth (RR 0.92, 95% CI 0.81 to 1.04; 10 trials; 3240 women).

Five trials compared administration of oral misoprostol with intracervical prostaglandin E2 (681 women). Oral misoprostol was associated with fewer instances of failure to achieve vaginal birth within 24 hours (RR 0.78, 95% CI 0.63 to 0.97; 3 trials; 452 women) but more frequent uterine hyperstimulation with fetal heart rate changes (RR 3.57, 95% CI 1.11 to 11.54; 3 trials; 490 women). The available data for this comparison were however limited and the differences in caesarean birth were small (RR 0.85, 95% CI 0.63 to 1.16; 5 trials; 742 women).

Nine trials compared oral misoprostol with intravenous oxytocin (1282 women). There were no obvious differences in the frequency of: vaginal birth within 24 hours (RR 0.79, 95% CI 0.59 to 1.05; 6 trials; 789 women), or uterine hyperstimulation with fetal heart rate changes (RR 1.30, 95% CI 0.43 to 3.91; 7 trials; 947 women). There were, however, fewer caesarean births with oral misoprostol (RR 0.77, 95% CI 0.60 to 0.98; 9 trials; 1282 women).

Thirty-seven trials compared oral misoprostol with vaginal misoprostol (6417 women). There was little difference in the frequency of: vaginal birth within 24 hours (RR 1.08, 95% CI 0.86 to 1.36; 14 trials; 2,448 women), uterine hyperstimulation with fetal heart rate changes (RR 0.71, 95% CI 0.47 to 1.08; 29 trials; 5,503 women), and caesarean birth (RR 0.93, 95% CI 0.81 to 1.07; 35 trials; 6,326 women).

The incidence of serious neonatal or maternal morbidity or death was rare and no meaningful results were available for any of the comparisons.

Authors' conclusions

Oral misoprostol as an induction agent is effective at achieving vaginal birth. It is more effective than placebo, as effective as vaginal misoprostol and vaginal dinoprostone, and results in fewer caesarean sections than oxytocin alone.

Where misoprostol remains unlicensed for the induction of labour, many practitioners will prefer to use a licensed product like dinoprostone. If using oral misoprostol, the evidence suggests that the dose should be 20 to 25 mcg in solution. Given that safety is the primary concern, the evidence supports the use of oral regimens over vaginal regimens. This is especially important in situations where the risk of ascending infection is high and the lack of staff means that women cannot be intensely monitored.

PLAIN LANGUAGE SUMMARY

Oral misoprostol for induction of labour

Oral misoprostol is effective at inducing (starting) labour. It is more effective than placebo, as effective as vaginal misoprostol and vaginal dinoprostone, and results in fewer caesarean sections than oxytocin. However, there are still not enough data from randomised controlled trials to determine the best dose to ensure safety.

Induction of labour in late pregnancy is used to prevent complications when the pregnant woman or her unborn child are at risk. Reasons for induction include being overdue, pre-labour rupture of membranes and high blood pressure. Prostaglandins are hormones that are naturally present in the uterus (womb); they soften the cervix and stimulate contractions in labour. The artificial prostaglandin E2 dinoprostone can be administered vaginally to induce labour but it is unstable at room temperature and is expensive. Oral misoprostol is a cheap and heat stable prostaglandin E1 synthetic analogue originally developed for the treatment of stomach ulcers.

The search for trials took place in January 2014. This review of 75 randomised controlled trials (13,793 women) found that oral misoprostol appears to be at least as effective as current methods of induction.

Nine trials (1,282 women) showed that oral misoprostol was equivalent to intravenous infusion of oxytocin. There were no obvious differences in the number of women who had a vaginal birth within 24 hours, or the number of women who experienced uterine hyperstimulation with changes to the baby's heart rate, although there were fewer caesarean sections in the group of women who were given oral misoprostol.

For the 37 thirty seven trials (6,417 women) that compared oral and vaginal misoprostol, there was little difference in the number of women who had a vaginal birth within 24 hours, uterine hyperstimulation with changes to the baby's heart rate, or caesarean section.

In 10 trials (3,240 women) comparing oral misoprostol with a vaginal prostaglandin (dinoprost), there was little difference in the frequency of vaginal birth within 24 hours, uterine hyperstimulation with changes to the baby's heart rate, or caesarean section.

The nine trials that compared oral misoprostol with placebo (1,109 women) and found that oral misoprostol is more effective than placebo for inducing labour. Women in the oral misoprostol group were more likely to have vaginal birth within 24 hours, and less likely to have a caesarean section. There was little difference between groups in terms of the number of women who experienced uterine hyperstimulation with changes to the baby's heart rate.

Five trials compared oral misoprostol with intracervical (inserted into the entrance of the womb) prostaglandin E2 (681 women). Oral misoprostol was associated with fewer instances of failure to achieve vaginal birth within 24 hours but more frequent uterine hyperstimulation with changes to the baby's heart rate. The available data for this comparison was limited and the differences in caesarean birth were small.

Overall, the incidence of serious illness or death of the mother or her baby was rare and no meaningful results were available for any of the comparisons in this review.

Using oral misoprostol to induce labour is effective at achieving vaginal birth. It is more effective than placebo, as effective as vaginal misoprostol and vaginal dinoprostone, and results in fewer caesarean sections than using oxytocin alone.

In some countries where misoprostol is not licenced for the purpose of inducing labour, many clinicians may prefer to use some other licensed product such as dinoprostone. Where oral misoprostol is used, evidence suggests that an appropriate dose may be 20 to 25 mcg in solution. Given that safety is the primary concern, the evidence supports the use of oral regimens over vaginal regimens. This is particularly important in settings where the mother is at a higher risk of infection and where there may be insufficient staff to closely monitor the mother and her baby.

BACKGROUND

This review is one of a series of reviews of methods of labour induction using a standardised protocol. For more detailed information on the rationale for this methodological approach, please refer to the currently published 'generic' protocol (Hofmeyr 2009). The generic protocol describes how a number of standardised reviews will be combined to compare various methods of preparing the cervix of the uterus and inducing labour.

Induction of labour is a common clinical situation. The reasons for an induction are either clinical (post-term pregnancy, prelabour rupture of membranes, hypertensive disorders) or social (parents' and clinicians' convenience).

Prostaglandins have been widely used for labour induction, particularly if the cervix is not 'favourable' (Keirse 1993). Prostaglandin E2 (PGE2 or dinoprostone) appears to be the prostaglandin of choice when used vaginally in the form of gel, tablets or pessaries. Unfortunately, vaginal PGE2 preparations are expensive and unstable at room temperature.

Oral administration of prostaglandins is less effective (Keirse 1989) and has been virtually abandoned, mainly due to gastrointestinal side effects. However, interest in oral prostaglandins has increased with the introduction of a new synthetic prostaglandin E1 analogue - misoprostol. This drug is used mainly for the prevention and treatment of nonsteroidal anti-inflammatory drug-induced ulcers of the digestive tract. It is relatively cheap and stable at room temperature. Used for this indication, oral misoprostol is usually given in two to four doses of 200 micrograms (mcg) per day and the time to maximum concentration is 10 to 20 minutes (versus 60 to 80 minutes in the case of vaginal administration, Abdel-Aleem 2003). Side effects are dose dependent and are mainly confined to the digestive tract, such as diarrhoea and nausea (Garris 1989).

Uterine contractions induced by misoprostol are often strong enough to expel products of conception in early pregnancy. Widespread use of misoprostol in Brazil for termination of pregnancy (Costa 1993) resulted in the identification of teratogenic effects including abnormalities of extremities (clubfoot, agenesis of the feet and hands, syndactyly, constriction rings) and Mobius sequence (loss of function of the motor cranial nerves, especially VI, VII and XII) (Fonseca 1991; Gonzales 1999; Pastuszak 1998). These defects affect less than 1% of exposed fetuses (Philip 2002). Maternal death from uterine rupture at 16 weeks' gestation after self-medication with misoprostol has been reported (Costa 1993).

Randomised trials, which have evaluated the effectiveness of a vaginally administered misoprostol for labour induction with a viable fetus, have been reviewed for *The Cochrane Library* (Hofmeyr 2010). Oral use is particularly attractive because of easy and non-invasive administration. However, there are inherent risks of such an approach. An overdose, causing uterine hyperstimulation may precipitate labour, and may be life-threatening for both mother and fetus. It is therefore, important that oral misoprostol is evaluated in a systematic fashion to assess if it can be recommended for routine clinical practice.

Despite having been widely studied for several reproductive health indications, misoprostol's licence has never been extended. This is thought to be due to the manufacturer's concerns about potential adverse publicity generated by the powerful US anti-abortion lobby. Off-label drug use is common in obstetrics, and includes many drugs, which would be considered mandatory in everyday practice (e.g. corticosteroids to prevent neonatal respiratory distress syndrome after premature labour and oxytocin 10 international units intramuscularly to prevent postpartum haemorrhage). Despite this, many practitioners are concerned about the potential legal consequences of using an off-label drug should a serious adverse event occur, especially if an effective licensed alternative is available (Weeks 2005). Now that the patent for misoprostol has expired, generic misoprostol products licensed for reproductive health indications have become available in various parts of the world such as Brazil, France and Egypt. The arrival of licensed products will ease the medico-legal concerns of those wishing to use misoprostol for induction of labour.

Description of the condition

Induction of labour is used to bring an end to pregnancy when the benefits of giving birth at that time outweigh the risks of the induction process.

Description of the intervention

Oral misoprostol is given as a regular medication to pregnant women either as a tablet or in solution. The dosage and form of the medication varies, but it is generally used only until the woman's cervix is fully ripened. If further uterine stimulation is required after this, an intravenous infusion of oxytocin is generally used until birth, although some studies have continued the use of low-dose misoprostol.

How the intervention might work

Similar to other prostaglandins, oral misoprostol acts on the uterus to soften (or 'ripen') the cervix and to stimulate contractions.

Why it is important to do this review

Oral misoprostol is a low-cost and effective method for induction which is in common use in many parts of the world. Until recently, the drug was not licensed for use in pregnancy and so the drug manufacturers had neither formally evaluated it nor packaged the drug for induction of labour. There has been confusion therefore over which misoprostol regimen to use, and the use of excessive doses in late pregnancy has been thought to have been responsible for serious complications including uterine rupture. A formal evaluation of the many published studies is therefore very important to guide national and international recommendations for its appropriate use.

OBJECTIVES

To determine, from randomised controlled trials, the effectiveness and safety of oral misoprostol for third trimester induction of labour.

METHODS

Criteria for considering studies for this review

Types of studies

Clinical trials comparing oral misoprostol for labour induction with placebo/no treatment or other methods for labour induction. Quasi-randomised trials were not included. This review includes

only induction methods listed above oral misoprostol on a predefined list of methods of labour induction (see Data collection and analysis). We have included only trials that have some form of random allocation to the study groups and report at least one of the prestated outcomes. We have also included studies that compare various oral misoprostol regimens.

In this review we make no distinction between cervical ripening and induction of labour if the aim was to achieve vaginal birth as safely as possible. However, we excluded the studies if the primary aim of intervention was to 'facilitate' spontaneous onset of labour over a long period of time (for example, oral misoprostol every other day between 40 and 42 weeks' gestation).

Types of participants

Pregnant women due for third trimester induction of labour who carry a viable fetus.

Types of interventions

Oral misoprostol compared with placebo/no treatment or six other methods for labour induction placed above oral misoprostol on a predefined list (see Data collection and analysis):

1. placebo/no treatment;
2. vaginal prostaglandin E2;
3. intracervical prostaglandin E2;
4. oxytocin alone;
5. amniotomy alone;
6. amniotomy + oxytocin;
7. vaginal misoprostol.

We will not discuss any of the comparisons listed above without relevant trials in this review. For the details of this selection strategy, please refer to Data collection and analysis.

In previously published versions of this review, we proposed to compare low-, medium- and high-dose regimens. We defined low-dose regimens as less than 50 micrograms (mcg), medium-dose as 50 to 100 mcg inclusive and high-dose as more than 100 mcg. These arbitrary groups proved impractical because most trials used either 25 mcg, 50 mcg or 100 mcg doses. In order to study dose-related effects, we decided to group regimens into: (i) 0 to 25 mcg, (ii) 26 to 50 mcg, (iii) 51 to 199 mcg and (iv) 200 mcg or more. We acknowledge that this change has been driven to some extent by the trials' data and is therefore a potential source of bias. Also, the same dose can be given at varying intervals (usually between two and six hours) and these differences could influence the primary outcomes. 'Low-dose' regimens with two-hourly administration may result in a higher cumulative dose over 24 hours than 'high-dose' regimens. However, the plasma half-life of oral misoprostol is short (20 to 40 minutes) and, therefore, it would appear that dose is more important than frequency. Consequently, at least at this point in time, we have not planned analyses based on frequency of administration.

Types of outcome measures

Two authors of labour induction reviews (Justus Hofmeyr and Zarko Alfirevic) prespecified the clinically relevant outcomes for trials of methods of cervical ripening/labour induction. After discussion a consensus has been reached by all registered Cochrane Pregnancy and Childbirth Group review authors with an interest in labour induction.

Primary outcomes

We chose five primary outcomes as being most representative of the clinically important measures of ineffectiveness and complications:
(1) vaginal delivery not achieved within 24 hours (includes all caesarean sections);
(2) uterine hyperstimulation with fetal heart rate (FHR) changes;
(3) caesarean section;
(4) serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood);
(5) serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia).

Perinatal and maternal morbidity and mortality are composite outcomes. This is not an ideal solution because some components are clearly less severe than others. It is possible for one intervention to cause more deaths but fewer babies with severe morbidity. However, in the context of labour induction at term this is unlikely. All these events will be rare, and a modest change in their incidence will be easier to detect if composite outcomes are presented. We will explore the incidence of individual components as secondary outcomes.

Secondary outcomes

Secondary outcomes relate to measures of clinical ineffectiveness, complications and satisfaction.

Measures of ineffectiveness:
(6) cervix unfavourable/unchanged after 12 to 24 hours;
(7) oxytocin augmentation.

Complications:
(8) uterine hyperstimulation without FHR changes;
(9) uterine rupture;
(10) epidural analgesia;
(11) instrumental vaginal delivery;
(12) meconium-stained liquor;
(13) Apgar score less than seven at five minutes;
(14) neonatal intensive care unit admission;
(15) neonatal encephalopathy;
(16) perinatal death;
(17) disability in childhood;
(18) maternal side effects (all);
(19) maternal nausea;
(20) maternal vomiting;
(21) maternal diarrhoea;
(22) other maternal side effects;
(23) postpartum haemorrhage (as defined by the trial authors);
(24) serious maternal complications (e.g. intensive care unit admission, septicaemia but excluding uterine rupture);
(25) maternal death.

Measures of satisfaction:
(26) woman not satisfied;
(27) caregiver not satisfied.

'Uterine rupture' includes all clinically significant ruptures of unscarred or scarred uteri. We have excluded asymptomatic scar dehiscence noted incidentally at the time of surgery.

While we have sought all of the above outcomes, only those with data appear in the analysis tables.

The terminology of uterine hyperstimulation is problematic (Curtis 1987). In the reviews we use the term 'uterine hyperstimulation without FHR changes' to include uterine tachysystole (more than five contractions per 10 minutes for at least 20 minutes) and uterine hypersystole/hypertonus (a contraction lasting two minutes or more) and 'uterine hyperstimulation with FHR changes' to denote uterine hyperstimulation syndrome (tachysystole or hypersystole with fetal heart rate changes such as persistent decelerations, tachycardia or decreased short-term variability).

Outcomes are included in the analysis if data were available according to original allocation and reasonable measures were taken to minimise observer bias.

Only outcomes with available data appear in the analysis tables. We have, nevertheless, extracted and reported data on outcomes that were not prestated above. However, we have clearly labelled them as such ('not prespecified'). In order to minimise the risk of bias, we have based the conclusions solely on the prestated outcomes.

The methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (17 January 2014).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE
3. weekly searches of Embase;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and Embase, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions, and included data from abstracts so long as there was sufficient information on the study method, population and outcomes.

Data collection and analysis

To avoid duplication of data in a series of reviews on interventions for labour induction as described in the generic protocol for methods for cervical ripening and labour induction in late pregnancy (Hofmeyr 2009), the labour induction methods were listed in a specific order, from one to 27. Each review included comparisons between one of the methods (from two to 27) with only those methods above it on the list. Thus, this review of oral misoprostol (8) could include comparisons with any of the following: (1) placebo/no treatment; (2) vaginal prostaglandins; (3) intracervical prostaglandins; (4) intravenous oxytocin; (5) amniotomy; (6) intravenous oxytocin with amniotomy; (7) vaginal misoprostol. The current list is as follows:

(1) placebo/no treatment;
(2) vaginal prostaglandins (Kelly 2009);
(3) intracervical prostaglandins (Boulvain 2008);
(4) intravenous oxytocin (Alfirevic 2009);
(5) amniotomy (Bricker 2000);
(6) intravenous oxytocin with amniotomy (Bimbashi 2012; Howarth 2001);
(7) vaginal misoprostol (Hofmeyr 2010);
(8) oral misoprostol (this review);
(9) mechanical methods including extra-amniotic Foley catheter (Jozwiak 2012);
(10) membrane sweeping (Boulvain 2005);
(11) extra-amniotic prostaglandins (Hutton 2001);
(12) intravenous prostaglandins (Luckas 2000);
(13) oral prostaglandins (French 2001);
(14) mifepristone (Hapangama 2009);
(15) oestrogens with or without amniotomy (Thomas 2001);
(16) corticosteroids (Kavanagh 2006a);
(17) relaxin (Kelly 2013);
(18) hyaluronidase (Kavanagh 2006b);
(19) castor oil, bath, and/or enema (Kelly 2013a);
(20) acupuncture (Smith 2013);
(21) breast stimulation (Kavanagh 2005);
(22) sexual intercourse (Kavanagh 2001);
(23) homoeopathic methods (Smith 2003);
(24) nitric oxide donors (Kelly 2011);
(25) buccal or sublingual misoprostol (Muzonzini 2004);
(26) hypnosis (Nishi 2013);
(27) other methods for induction of labour.

The reviews were analysed by the following clinical categories of participants:

1. previous caesarean section or not;
2. nulliparity or multiparity;
3. membranes intact or ruptured;
4. cervix favourable, unfavourable or undefined.

For most reviews, the initial data extraction process was conducted centrally. This was co-ordinated from the Clinical Effectiveness Support Unit (CESU) at the Royal College of Obstetricians and Gynaecologists, UK, in co-operation with the Pregnancy and Childbirth Group of The Cochrane Collaboration. This process allowed the data extraction process to be standardised across all the reviews. From 2001, the data extraction was no longer conducted centrally.

The trials were initially reviewed on eligibility criteria, using a standardised form and the basic selection criteria specified above. Following this, a standardised data extraction form was developed and then piloted for consistency and completeness. This pilot process involved the researchers at the CESU and previous review authors in the area of induction of labour. For a description of the methods used to carry out the initial reviews, see Hofmeyr 2009.

For this update we used the following methods when assessing the reports identified by the updated search.

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion with the third author.

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We resolved discrepancies through discussion with the third author. We entered data into Review Manager software (RevMan 2012) and checked it for accuracy.

When information regarding any of the above is unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving the third author.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported

incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we have about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

We did not analyse any continuous data in this update. In future updates, if we include continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We did not include any cluster-randomised trials in this update. If included in future updates, we will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook [Section 16.3.4 or 16.3.6]* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity or subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

Cross-over trials are not eligible for inclusion in this review.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if an I^2 was greater than 30% and either the Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

Funnel plots were not used to assess reporting bias.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2012). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we did not provide a summary statistic.

If random-effects analyses were used, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2.

Where the data allowed, the results were analysed by the following clinical categories of participants:

1. previous caesarean section or not;
2. nulliparity or multiparity;
3. membranes intact or ruptured;
4. cervix favourable, unfavourable or undefined.

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we investigated it using subgroup and sensitivity analyses. We considered whether an

overall summary was meaningful, and if it was, we used random-effects analysis to produce it (see details in Data synthesis).

In the main analysis ("all women") for each comparison (i.e. not on the clinical categories) we carried out the following subgroup analyses:

1. dose-related effects of oral misoprostol, regimens: 0 to 25 mcg versus 26 to 50 mcg versus 51 to 199 mcg versus 200 mcg or more.

The subgroup analysis was conducted for all outcomes within the main analysis.

We assessed subgroup differences by interaction tests available within RevMan (RevMan 2012). We reported the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

In the event of significant heterogeneity, we carried out sensitivity analyses to explore the effect of trial quality (judged according to the method and reporting of allocation concealment), with poor-quality studies (allocation concealment inadequate or not reported) being excluded from the analyses in order to assess whether this explained the heterogeneity. No other sensitivity analysis was conducted.

RESULTS

Description of studies

Results of the search

We have included 76 studies in the current review, containing a total of 14,412 women. Only 160 women in three studies had undergone previous caesarean section (Carlan 2001 (V50); How 2001 (V25); Patil 2005).

Included studies

Placebo/no treatment as comparator

Nine studies were categorised under this comparison. Only two studies compared oral misoprostol with no treatment (expectant management) (Javaid 2008; Rath 2007). In both studies only women with ruptured membranes were included and those randomised to the expectant group had no treatment for 20 to 24 hours. Seven studies compared oral misoprostol with placebo. Two of these studies used initial 50 mcg doses (Cheung 2006; Levy 2007); three studies used initial 100 mcg doses (Hoffman 2001; Lo 2003; Lyons 2001); and two used 200 mcg doses (Beigi 2003; Ngai 1996). In Cheung 2006, women were randomised three ways: to placebo, 50 mcg or 100 mcg misoprostol. As 50 mcg is the most commonly recommended dose for oral misoprostol, we chose to include only the outcomes for the placebo versus 50 mcg dose. We have also included the outcomes for the 50 mcg versus 100 mcg doses in that section of the review. In Hoffman 2001 women in both arms received dinoprostone after 12 hours if not in active labour. The participants all had ruptured membranes at term except in Beigi 2003, where women with intact membranes were also included.

Dinoprostone as comparator

In 10 studies, the comparison was with the prostaglandin dinoprostone administered vaginally (Dallenbach 2003 (T); Dodd 2006; Gherman 2001a; Henrich 2008 (T); Hofmeyr 2001(T); le Roux 2002 (V50); Majoko 2002 (V50); Moodley 2003; Shetty 2004; Tessier 1997). The studies included only women with intact membranes, except for Hofmeyr 2001(T), which also included women with ruptured membranes and Henrich 2008 (T) and Tessier 1997 did not specify the membrane status for the included women. The initial dosage of misoprostol was 50 mcg or less in all studies except for Shetty 2004, where 100 mcg was used. In Majoko 2002 (V50), the initial dose was 10 mcg and each successive four-hourly dose was doubled to a maximum of 400 mcg. In the studies by Dallenbach 2003 (T) and Hofmeyr 2001(T), women received 20 mcg oral misoprostol (dissolved in water) two-hourly for two doses and then 40 mcg two-hourly. Doses could also be given in labour if contractions slowed. In the studies by Moodley 2003 and Dodd 2006, women received 20 mcg of oral solution two-hourly. A third arm of the Moodley 2003 study, where women received an initial 25 mcg of vaginal misoprostol followed by 20 mcg oral misoprostol, is not included in this review.

Oral misoprostol was compared with intracervical dinoprostone in the studies by Bartha 2000 and Patil 2005 (both 200 mcg dose), as well as Langenegger 2005, Sheela 2007 (V25) and Nagpal 2009 (50 mcg dose). All studies included only women with intact membranes except for Nagpal 2009 which included only women with ruptured membranes.

In the Tessier 1997 study, 23 of the 267 women had undergone a caesarean section in a previous pregnancy.

Oxytocin as comparator

Nine studies compared oral misoprostol with oxytocin. In six, the women had ruptured membranes at term (Al-Hussaini 2003; Butt 1999; Crane 2003; Dodd 2006a (T); Mozurkewich 2003; Ngai 2000), whilst in two other trials women with intact membranes were also included (Nigam 2004; Wing 2004), and one study included a mix of women with ruptured and intact membranes (Aalami-Harandi 2013 (T)). In most trials the dose was 100 mcg. However, in Dodd 2006a (T) (abstract form only), an hourly dose of titrated oral solution starting with 5 mcg was used; in Butt 1999 and Nigam 2004, 50 mcg was used; and in Crane 2003, 75 mcg was used. Aalami-Harandi 2013 (T) used a 200 mcg tablet of misoprostol dissolved in 200 mL water, and administered 25 mL (25 mcg) every two hours.

Vaginal misoprostol as comparator

The most common comparison in this review is with vaginal misoprostol (37 studies). The figure in brackets after the study reference indicates the initial dosage of vaginal misoprostol used in the comparison. In 16 studies the participants had intact membranes (Adair 1998 (V50); Bennett 1998 (V50); Carlan 2001 (V50); Fisher 2001 (V50); Khazardoost 2011 (V25); Kwon 2001 (V50); le Roux 2002 (V50); Majoko 2002 (V50); Mehrotra 2010 (V50); Nopdonrattkaoon 2003 (V50); Paungmora 2004 (V50); Pongsatha 2005 (V50); Sheela 2007 (V25); Shetty 2001 (V50); Shetty 2003 (V25); Wing 1999 (V25)) and in three studies they had ruptured membranes (Jindal 2011 (V50); Puga 2001 (V50); Rizvi 2007 (V25)). Eleven studies included women with both intact and ruptured membranes (Cheng 2008 (T) (V25); Colon 2005 (V25); Deshmukh 2013 (V50); Dyar 2000 (V50); Hall 2002 (V25); Pais'wong 2008 (V25); Rahman 2013 (V25); Souza 2013(V25)(T); Toppozada 1997 (V100); Uludag 2005 (V50); Wing 2000 (V25)), whilst in six studies the membrane status was not clarified (Adam 2005 (V50); Elhassan 2007 (V50); Schneider 2004 (V25); Sheikher 2009 (V25);

Sitthiwattanawong 1999; Sultana 2006 (V100)). Most trials used a 50 mcg dose of oral misoprostol (16 studies), but three used 20 to 25 mcg (Cheng 2008 (T) (V25); How 2001 (V25); Souza 2013(V25) (T)), 11 used 100 mcg (Hall 2002 (V25); Khazardoost 2011 (V25); Paungmora 2004 (V50); Pongsatha 2005 (V50); Puga 2001 (V50); Rizvi 2007 (V25); Shetty 2003 (V25); Sultana 2006 (V100); Toppozada 1997 (V100; Uludag 2005 (V50); Wing 2000 (V25)) and two used 200 mcg (Adair 1998 (V50); Carlan 2001 (V50)). In Majoko 2002 (V50), the initial dose was 10 mcg and each successive four-hourly dose was doubled, to a maximum of 400 mcg. In Colon 2005 (V25), the initial dose was 50 mcg, but increased to 100 mcg for subsequent doses. The dosage of vaginal misoprostol varied from 25 mcg to 100 mcg. The initial dose of vaginal misoprostol is stated in mcg after the year of article publication.

Two studies (Carlan 2001 (V50); How 2001 (V25)) included women who had previous caesarean sections (131 and 27 respectively).

Sublingual misoprostol as comparator

There was just one study (Elhassan 2007 (V50)) which compared 50 mcg of oral, vaginal and sublingual misoprostol (50 women in each group).

Vaginal dinoprostone insert as comparator

One study (Rouzi 2014) compared titrated oral misoprostol solution at 20 mcg with a 10 mcg dinoprostone vaginal, inserted for a maximum of 24 hours.

Other comparisons

There were several other randomised trials comparing different oral misoprostol protocols. In one study Kipikasa 2005 compared 25 mcg and 50 mcg doses every three days for nine days. This study was conducted on an outpatient basis. Two studies compared 50 mcg and 100 mcg doses (Cheung 2006; Shetty 2002) and two studies by the same team examined frequency of dosaging. They initially compared 50 mcg given four-hourly or six-hourly (Pongsatha 2001) and then conducted a similar study comparing 100 mcg three-hourly and six-hourly (Pongsatha 2002). In this review, we have grouped together the dosage frequency studies with dosage subgroups.

One study compared a regimen of oral misoprostol 25 mcg given three-hourly until in labour (with oxytocin only if contractions settled) with a regimen of two oral misoprostol tablets followed by routine oxytocin (De 2006). Another examined two management policies for women with ruptured membranes at term (Shetty 2002a). One group received oral misoprostol 50 mcg four-hourly at recruitment and the other had conservative management for 24 hours followed by PGE2 1 to 2 mg six-hourly. The study by Thaisomboon 2012 (T) included only women with intact membranes. In this study, one group received hourly misoprostol solution 20 mcg (200 mcg tablet dissolved in 200 mL of tap water). If no uterine contractions were achieved after the first four doses the dose was doubled to 40 mcg up to a maximum of eight doses. The other group received misoprostol solution orally 50 mcg every four hours (20 mL of 200 mcg misoprostol in 80 mL water). The study was double blinded by the use of 20 mL of placebo solution between doses.

Excluded studies

Four exclusions are potentially controversial. We have excluded the study by Windrim 1997 because 138 women in the comparator group were induced with four different methods (intracervical dinoprostone, vaginal dinoprostone, oxytocin, vaginal misoprostol). We felt that these methods are too different to be compared to oral misoprostol as one intervention. Ascher-Walsh 2000 used oral misoprostol to achieve spontaneous onset of labour, i.e. oral misoprostol or placebo were given in three-day intervals between 40 and 42 weeks of pregnancy. This review with its clinical outcomes concentrates on methods to achieve vaginal birth as quickly as possible, so we decided to exclude this trial.The study by Zvandasara 2008 was excluded as it included women with intrauterine fetal death (four women). Finally,the study by Rasheed 2007 (V50) included data on 25 women who were not randomised.These women were undergoing induction of labour with oral misoprostol (their normal unit induction method) just before the trial started. We therefore included their data with the oral misoprostol arm within the data set from the 285 women who were in the randomised group. The additional data has resulted in an uneven balance between the groups (165 versus 145), and the data derived from those randomised alone are not retrievable from the manuscript.

A number of studies were excluded as they used a combination of techniques. We excluded the studies by Kadanali 1996 and Bricker 2008 because they used vaginal misoprostol followed by oral administration. These studies are therefore included in the Cochrane review of vaginal misoprostol by Hofmeyr 2003. The study by Neto 1988 concentrated on the uterine effects of oral and vaginal misoprostol. Five women received oral misoprostol in the dose of 200 mcg four-hourly, five women received 400 mcg four-hourly and five women received a single 200 mcg tablet vaginally. The reported outcomes included initiation, dynamics and duration of uterine contractions. Clinical outcomes were not reported and we have therefore excluded the study. We excluded Bozhinova 2007 as the comparison of oral misoprostol was with combined vaginal and sublingual misoprostol. Delaney 2001 was excluded as women had an artificial rupture of membranes performed at study entry and the oxytocin or oral misoprostol was only used for those who were not in labour one hour later.

We excluded Ho 2010 as it is a study of labour augmentation in women with 'failure to progress in labour' rather than labour induction.

As reported above, the study by Moodley 2003 had three arms. We have included outcomes from the groups treated with oral misoprostol and vaginal dinoprostone in this review, but not from the third group, where women received a mixture of oral and vaginal misoprostol.

Several studies are still ongoing (DebBarma 2013; Gherman 2002; Pranuthi 2011), awaiting translation or have not been not been reported fully yet (Atkinson 2000; Bonebrake 2001; Butler 2004; Getgan 2003; Goedken 2000; Madhavi 2011; Niroomanesh 2011; Pearson 2002; Saldivar 2001; Tuipae 1999; Vijitrawiwat 2003; Yazdani 2012; Young 2001).

Risk of bias in included studies

See Figure 1; Figure 2 for a summary of 'Risk of bias' assessments.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

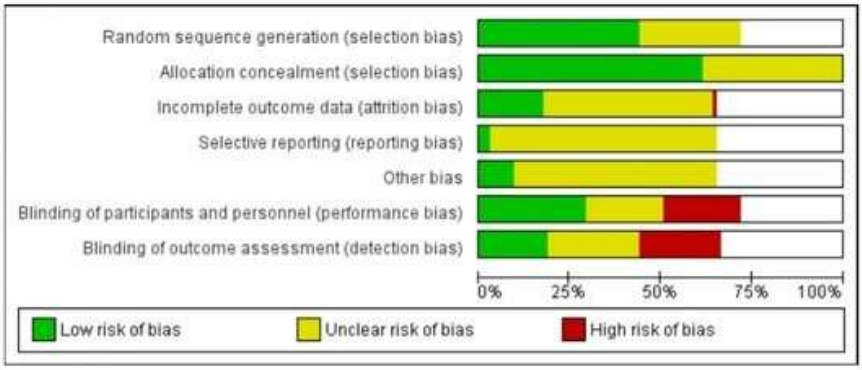

Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

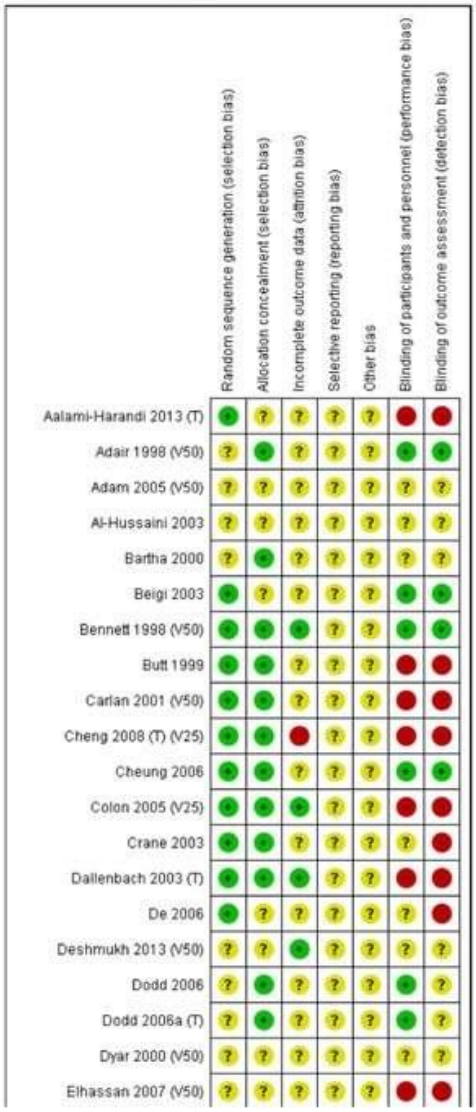

Figure 2. (Continued)

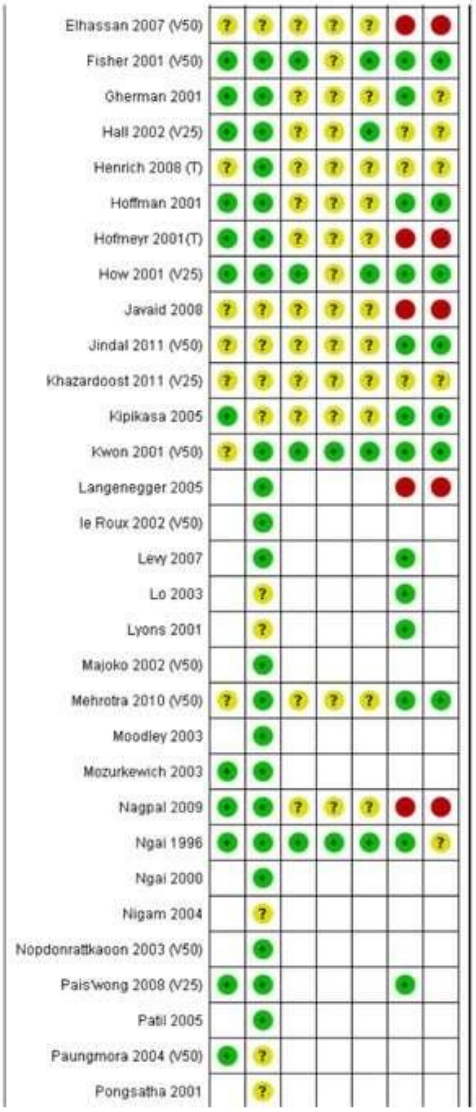

Figure 2. (Continued)

Allocation

Sequence generation

Thirty-three trials were assessed as being low risk of bias (Aalami-Harandi 2013 (T); Beigi 2003; Bennett 1998 (V50); Butt 1999; Carlan 2001 (V50); Cheng 2008 (T) (V25); Cheung 2006; Colon 2005 (V25); Crane 2003; Dallenbach 2003 (T); De 2006; Fisher 2001 (V50); Gherman 2001; Hall 2002 (V25); Hoffman 2001; Hofmeyr 2001(T); How 2001 (V25); Kipikasa 2005; Mozurkewich 2003; Nagpal 2009; Ngai 1996; Pais'wong 2008 (V25); Paungmora 2004 (V50); Rahman 2013 (V25); Rouzi 2014; Shetty 2002; Sitthiwattanawong 1999; Souza 2013(V25)(T); Tessier 1997; Thaisomboon 2012 (T); Toppozada 1997 (V100; Wing 1999 (V25); Wing 2004) for sequence generation. The method of randomisation was unclear in 21 trials (Adair 1998 (V50); Adam 2005 (V50); Al-Hussaini 2003; Bartha 2000; Deshmukh 2013 (V50); Dodd 2006; Dodd 2006a (T); Dyar 2000 (V50); Elhassan 2007 (V50); Henrich 2008 (T); Javaid 2008; Jindal 2011 (V50); Khazardoost 2011 (V25); Kwon 2001 (V50); Mehrotra 2010 (V50); Rath 2007; Rizvi 2007 (V25); Sheikher 2009 (V25); Sultana 2006 (V100); Uludag 2005 (V50); Wing 2000 (V25))

Allocation concealment

Forty-six trials were low risk of bias for allocation concealment (Adair 1998 (V50); Bartha 2000; Bennett 1998 (V50); Butt 1999; Carlan 2001 (V50); Cheng 2008 (T) (V25); Cheung 2006; Colon 2005 (V25); Crane 2003; Dallenbach 2003 (T); Dodd 2006; Dodd 2006a (T); Fisher 2001 (V50); Gherman 2001a; Hall 2002 (V25); Henrich 2008 (T); Hoffman 2001; Hofmeyr 2001(T); How 2001 (V25); Kwon 2001 (V50); Langenegger 2005; le Roux 2002 (V50); Levy 2007; Majoko 2002 (V50); Mehrotra 2010 (V50); Moodley 2003; Mozurkewich 2003; Nagpal 2009; Ngai 1996; Ngai 2000; Nopdonrattkaoon 2003 (V50); Pais'wong 2008 (V25); Patil 2005; Rahman 2013 (V25); Rouzi 2014; Shetty 2001 (V50); Shetty 2002; Shetty 2002a; Shetty 2003 (V25); Shetty 2004; Thaisomboon 2012 (T); Tessier 1997; Uludag 2005 (V50); Wing 1999 (V25); Wing 2000 (V25); Wing 2004). The following trials were assessed as unclear risk of bias for this domain (Aalami-Harandi 2013 (T); Adam 2005 (V50); Al-Hussaini 2003; Beigi 2003; De 2006; Deshmukh 2013 (V50); Dyar 2000 (V50); Elhassan 2007 (V50); Javaid 2008; Jindal 2011 (V50); Khazardoost 2011 (V25); Kipikasa 2005; Lo 2003; Lyons 2001; Nigam 2004; Paungmora 2004 (V50); Pongsatha 2001; Pongsatha 2002; Puga 2001 (V50); Rath 2007; Rizvi 2007 (V25); Schneider 2004 (V25); Sheela 2007 (V25); Sheikher 2009 (V25); Sitthiwattanawong 1999; Souza 2013(V25)(T); Sultana 2006 (V100); Toppozada 1997 (V100).

Blinding

Of the studies we included, 14 were at low risk of bias for both performance and detection bias (Adair 1998 (V50); Beigi 2003; Bennett 1998 (V50); Cheung 2006; Fisher 2001 (V50); Hoffman 2001; How 2001 (V25); Jindal 2011 (V50);Kipikasa 2005; Kwon 2001 (V50);Mehrotra 2010 (V50); Souza 2013(V25)(T); Tessier 1997; Thaisomboon 2012 (T)). Seven trials were at low risk performance bias but unclear risk of detection bias (Dodd 2006; Dodd 2006a (T); Lo 2003; Levy 2007; Lyons 2001; Ngai 1996; Pais'wong 2008 (V25)).

Fifteen trials were at a high risk of both performance and detection bias (Aalami-Harandi 2013 (T); Butt 1999; Carlan 2001 (V50); Cheng 2008 (T) (V25); Colon 2005 (V25); Dallenbach 2003 (T); Elhassan 2007 (V50); Hofmeyr 2001(T); Javaid 2008; Langenegger 2005; Nagpal 2009; Rahman 2013 (V25); Rouzi 2014; Sitthiwattanawong 1999; Wing 2004). Two trials were at unclear risk of performance bias but high risk of detection bias (Crane 2003; De 2006) and one trial was at high risk of performance bias and unclear risk of detection bias (Wing 2004). Fifteen trials were at unclear risk of both performance and detection bias (Adam 2005 (V50); Al-Hussaini 2003; Bartha 2000; Deshmukh 2013 (V50); Dyar 2000 (V50); Hall 2002 (V25); Henrich 2008 (T); Khazardoost 2011 (V25); Rath 2007; Rizvi 2007 (V25); Sheikher 2009 (V25); Sultana 2006 (V100); Uludag 2005 (V50); Wing 1999 (V25); Wing 2000 (V25)).

Where the treatment was not blinded there is a real possibility of bias, both in clinical decision making and assessment of outcomes. A clinician with a prior belief that oral misoprostol is effective and safe might be less likely to perform a caesarean section in case of fetal distress or slow labour. On the other hand, a clinician who is anxious about possible risks of the new treatment may be more likely to intervene.

Incomplete outcome data

There was wide variation in the outcomes reported in the studies, and some were not consistent with the outcomes in this review. So whilst 'vaginal birth within 24 hours' is an important summary primary outcome in this review, it is rarely used by trialists, many of whom prefer a continuous variable of time to birth (which is not one of the Cochrane outcomes). Similarly not all published papers use the strict Cochrane definition of hyperstimulation with or without fetal heart rate abnormalities despite these being important outcomes. In assessing these outcomes, the authors have had to use judgement in matching the reported outcomes (for example "hyperstimulation") with the predefined Cochrane outcomes. Increasingly, however, trialists are turning to the Cochrane reviews for their selection of outcomes, and so recent high-quality studies are well matched to the Cochrane outcomes set.

Selective reporting

There is a wide variation in reported outcomes, but no evidence of selective reporting was found.

Other potential sources of bias

None.

Effects of interventions

(1) Comparison with placebo (analyses 1 to 4)

Nine trials with 1109 participating women in total compared oral misoprostol with placebo or no treatment.

Primary outcomes: women using oral misoprostol were more likely to give birth vaginally within 24 hours (although this was only assessed in one trial of 96 women (risk ratio (RR) 0.16, 95% confidence interval (CI) 0.05 to 0.49) in which women in both arms were given dinoprostone after 12 hours), Analysis 1.1. Oral misoprostol was associated with lower caesarean section (CS) rates (RR 0.72, 95% CI 0.54 to 0.95), Analysis 1.3.

Secondary outcomes: oral misoprostol was also associated with less oxytocin augmentation (RR 0.42, 95% CI 0.37 to 0.49), Analysis 1.7, fewer admissions to the neonatal intensive care unit (RR 0.42, 95% CI 0.32 to 0.56), Analysis 1.14, and lower rates of epidural use (RR 0.81, 95% CI 0.69-0.96) Analysis 1.6 There were no other clinically important differences in prespecified outcomes, including measures of uterine hyperstimulation. Most of the women studied had ruptured membranes, and analysis confined to this subgroup demonstrated similar findings to the overall analysis.

Subgroups: in the subgroup of all women with ruptured membranes, there was a significant increase in the number of women with a vaginal birth within 24 hours (one study of 96 women, RR 0.16, 95% CI 0.05 to 0.49), Analysis 3.1. In the subgroups of all women with intact membranes and primigravid women with ruptured membranes, there were no significant changes in the primary outcomes.

(2) Comparison with vaginal dinoprostone (analyses 5 to 11)

A total of 3,240 women were randomised to oral misoprostol or vaginal dinoprostone in 10 trials. The most common dose of misoprostol used in these studies was 20 mcg oral solution given two-hourly.

Primary outcomes: there was no effect on CS rate in those treated with oral misoprostol (RR 0.92, 95% CI 0.81 to 1.04), Analysis 5.3 or in the number of women not achieving vaginal birth within 24 hours (RR 1.09, 95% CI 0.99 to 1.20), Analysis 5.1,

Secondary outcomes: women treated with misoprostol more frequently had an unchanged cervix after 12 to 24 hours (RR 1.41, 95% CI 1.01 to 1.96), Analysis 5.6. There were no other statistically significant differences between the groups in any of the outcomes, including hyperstimulation rates and frequency of meconium-stained liquor.

Subgroups: six trials (n = 2,129) provided the data for a subgroup of women with intact membranes. The data show that women induced with misoprostol have fewer CSs (RR 0.85, 95% CI 0.73 to 0.99), Analysis 6.3. However, they had slower labours with increased rates of unchanged cervix after 12 to 24 hours (RR 1.51, 95% CI 1.03 to 2.20), Analysis 6.6 and a lower rate of vaginal birth within 24 hours (RR 1.12, 95%CI 1.01-1.25) Analysis 6.1. There were no other significant differences.

Only two trials provided the data for women with ruptured membranes and there were only data for two outcomes. The number of women who did not achieve vaginal birth within 24 hours was reduced in the misoprostol group (RR 0.60, 95% CI 0.37 to 0.97), Analysis 7.1, i.e. induction with oral misoprostol achieved vaginal birth within the first 24 hours more frequently compared with vaginal dinoprostone. There were no other significant differences in primary outcomes between the subgroups.

Only one study recruited women with previous CSs (n = 267) of which 23 had previous CS. No uterine ruptures were reported.

(3) Comparison with intracervical prostaglandin E2 (analyses 12, 13 and 14)

This comparison was found in five trials, involving 681 women randomised to oral misoprostol or intracervical dinoprostone. Four trials included only women with intact membranes and one included only women with ruptured membranes. Three used misoprostol doses of 50 mcg (352 women) and two used 200 mcg (two trials, 390 women).

Primary outcomes: the rate of uterine hyperstimulation with fetal heart rate (FHR) changes was significantly higher in those treated with misoprostol (RR 3.57, 95% CI 1.11 to 11.54), Analysis 12.2. However, significantly more women in the oral misoprostol group achieved vaginal birth within 24 hours (39% versus 49%, RR 0.78, 95% CI 0.63 to 0.97), Analysis 12.1.

Secondary outcomes: the rate of uterine hyperstimulation without FHR changes was significantly higher in those treated with misoprostol (RR 6.25, 95% CI 1.14 to 34.31), Analysis 12.8. Only one study considered maternal dissatisfaction, and this was lower in those treated with oral misoprostol (RR 0.51, 95% CI 0.27 to 0.96), Analysis 12.19. There were no other differences between the groups.

Subgroups: the subgroups for those with intact membranes found the oral misoprostol group to have a significantly higher rate of uterine hyperstimulation with FHR changes (RR 4.60, 95% CI 1.19 to 17.80), Analysis 13.2. There was an increase in the number of women with a vaginal birth within 24 hours but this was not statistically significant (RR 0.81, 95% CI 0.65 to 1.00), Analysis 13.1. In the subgroup with ruptured membranes, there was only one study and this showed no significant difference in any of the primary outcomes.

There was substantial heterogeneity for the 'need for oxytocin' outcome (I^2 = 80%), Analysis 12.7. Sensitivity and subgroup analysis indicated that this was not related to the poor quality study or dose.

(4) Comparison with intravenous oxytocin (analyses 15, 16, 17, 18 and 19)

Nine trials including 1282 women have compared oral misoprostol with intravenous oxytocin. Five studies used 100 mcg (818 women), two studies used 50 mcg (178 women), one used 20 mcg solution (30 women) and one study used 25 mcg solution (256 women).

Primary outcomes: the CS rate was significantly lower in women who received oral misoprostol (RR 0.77, 95% CI 0.60 to 0.98), Analysis 15.3, but there were no significant differences seen in any of the other primary outcomes. However, the meta-analysis of uterine hyperstimulation syndrome indicated substantial heterogeneity, Analysis 15.2. This may be explained by the trial by Crane 2003. which used a dose of 75 mcg four-hourly. That study found significantly less hyperstimulation with misoprostol, whilst the remainder found no difference.

Secondary outcomes: meconium staining of the liquor was seen more frequently in the misoprostol group (RR 1.65, 95% CI 1.04 to 2.60), Analysis 15.11, but this was not reflected in significant differences in any adverse fetal or neonatal outcomes.There were no other statistically significant differences between the oral misoprostol and intravenous oxytocin groups (except for oxytocin use, which was naturally higher in the oxytocin group).

Subgroups: in six of the trials (758 women) there were outcome data for women with ruptured membranes. In this subgroup, the percentage of women with meconium-stained liquor (and the RR) was similar to that in the overall results (Analysis 15.11), but the reduced numbers meant that the difference was not statistically significant (RR 1.71, 95% CI 0.91 to 3.23), Analysis 16.6.

There were no data reported for the subgroup of women with intact membranes.

(5) Comparison with sublingual misoprostol (analysis 20)

There was just one study of poor methodological quality in this comparison which compared 50 mcg of oral, vaginal and sublingual misoprostol (50 in each group, Elhassan 2007 (V50)). There was no significant difference in CS rate, but the oral misoprostol group had significantly higher rates of meconium-stained liquor than the sublingual misoprostol group (RR 10.50, 95% CI 4.07 to 27.09), Analysis 20.2, and significantly lower rates of instrumental vaginal birth (RR 0.47, 95% CI 0.22 to 0.99), Analysis 20.3.

(6) Comparison with vaginal misoprostol (analyses 21 to 29)

This was the most commonly studied comparison, with 37 trials and 6417 randomised women.

Primary outcomes: the overall outcome for the rate of uterine hyperstimulation *with* FHR changes was highly heterogenous. The interaction test indicated that there was a significant difference between dosage subgroups (Test for subgroup differences: Chi^2 = 18.50, df = 3 (P = 0.0003), I^2 = 83.8%) with less hyperstimulation in the 25 mcg oral misoprostol dose (RR 0.30, 95% CI 0.07 to 1.19), rising to an increase in hyperstimulation with the 200 mcg oral misoprostol dose (RR 1.61, 95% CI 1.07 to 2.43), Analysis 21.2.

Sensitivity analysis revealed that the overall result was not affected by the removal of low-quality studies.

The overall outcome for vaginal birth within 24 hours was also highly heterogenous, Analysis 21.1, but the interaction test did not indicate a subgroup difference in relation to oral misoprostol dosage. Sensitivity analysis with removal of the low-quality studies did not explain the heterogeneity.

The overall outcomes for the CS rate was also heterogenous (Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 60.78$, df = 34 (P = 0.003); $I^2 = 44\%$), Analysis 21.3. The heterogeneity was not affected by the removal of low-quality studies and the interaction test showed that there was no significant interaction between dosage subgroups.

There were no other significant findings in the two remaining primary outcomes.

Secondary outcomes: when all the data are considered together, the only statistically significant differences without heterogeneity were a reduction in the Apgars of less than seven at five minutes in the oral misoprostol group (RR 0.60, 95% CI 0.44 to 0.82), Analysis 21.13, and a decrease in postpartum haemorrhage (RR 0.57, 95% CI 0.34 to 0.95), Analysis 21.21. However, the oral misoprostol group had an increase in meconium-stained liquor (RR 1.22, 95% CI 1.03 to 1.44), Analysis 21.12.

The overall outcome for the rate of uterine hyperstimulation *without* FHR changes was also highly heterogenous, Analysis 21.8. The heterogeneity was not affected by the removal of low-quality studies and the interaction test showed that there was no significant interaction between dosage subgroups.

The overall outcome for the use of oxytocin was also highly heterogenous, and the interaction test showed that there was a significant dosage subgroup interaction (Test for subgroup differences: $Chi^2 = 9.10$, df = 3 (P = 0.03), $I^2 = 67.0\%$), Analysis 21.7. However, this was not in a dose-dependent manner. The heterogeneity was not affected by the removal of low-quality studies.

No uterine ruptures were reported in the women who had previous CSs.

Subgroups:

Intact membranes (analyses 22, 24, 27)

Seventeen of the 34 trials gave data for women with intact membranes. As with the overall data, there was no difference in any of the primary outcomes. The outcomes for vaginal birth not achieved in 24 hours and uterine hyperstimulation with FHR changes showed significant heterogeneity. Only one study examined the effect on vaginal birth within 24 hours in women with intact membranes (Wing 1999 (V25)) according to parity. That study showed a significant worsening in primigravid women given oral misoprostol (RR 1.25, 95% CI 1.01 to 1.55), Analysis 24.1, but not in multiparous women (RR 1.41, 95% CI 0.94 to 2.11), Analysis 27.1.

Fifteen trials that reported uterine hyperstimulation with FHR changes showed no significant change in hyperstimulation in the oral misoprostol group (average RR 0.83, 95% CI 0.46 to 1.52; Heterogeneity: $Tau^2 = 0.33$; $Chi^2 = 22.75$, df = 11 (P = 0.02); $I^2 = 52\%$), Analysis 22.2. However, there was significant heterogeneity in the results, with a significant association with dosage. The two 200 mcg studies had a significantly higher rate of uterine hyperstimulation with FHR changes and removing them from the analysis removed the overall heterogeneity and left the results as (RR 0.41, 95% CI 0.19 to 0.91).

Ruptured membranes (analysis 25)

Only two trials reported women with ruptured membranes as a subgroup (Jindal 2011 (V50); Puga 2001 (V50)). The only two reported primary outcomes (CS and uterine hyperstimulation with FHR changes) showed no significant difference between oral and vaginal routes, Analysis 25.1; Analysis 25.2.

Primiparae (analyses 24)

Only three trials reported outcomes for this subgroup. An increase in the number of women who did not birth vaginally within 24 hours was seen in the trial by Wing 1999 (V25), in which a 50 mcg dose was used in primips with intact membranes and an unfavourable cervix (RR 1.25, 95% CI 1.01 to 1.55), Analysis 24.1.

Multiparae (analyses 27)

Only two trials analysed this subgroup of women separately (Hall 2002 (V25); Toppozada 1997 (V100)) and they found no difference in the four reported outcomes, Analysis 27.1; Analysis 27.2; Analysis 27.3; Analysis 27.4.

(7) Hourly 20 mcg titrated oral misoprostol versus four-hourly oral misoprostol 50 mcg (analysis 30)

One study of 64 women compared the effect of using hourly 20 mcg solution and four-hourly 50 mcg solution (Thaisomboon 2012 (T)). There were no differences in any of the 12 outcomes, Analysis 30.1; Analysis 30.2; Analysis 30.3; Analysis 30.4; Analysis 30.5; Analysis 30.6; Analysis 30.7; Analysis 30.8; Analysis 30.9; Analysis 30.10; Analysis 30.11; Analysis 30.12.

(8) Oral misoprostol 25 mcg three-daily versus 50 mcg three-daily (analysis 31)

In one study (Kipikasa 2005), single oral doses of misoprostol were given every three days to women as outpatients. In this study there was no significant difference in any of the reported outcomes, Analysis 31.1; Analysis 31.2; Analysis 31.3; Analysis 31.4; Analysis 31.5; Analysis 31.6; Analysis 31.7; Analysis 31.8; Analysis 31.9; Analysis 31.10; Analysis 31.11; Analysis 31.12; Analysis 31.13; Analysis 31.14; Analysis 31.15.

(9) Oral misoprostol 50 mcg versus 100 mcg (analyses 32, 33, 34)

Two studies containing 317 women addressed the relationship between the 50 and 100 mcg doses (Cheung 2006; Shetty 2002). There were no significant differences between the 50 mcg and 100 mcg oral doses in any of the 11 outcomes assessed.

(10) Oral misoprostol 50 mcg, three- to four-hourly versus six-hourly (analyses 35, 36)

Two trials compared the outcomes when women were given oral tablets either three- to four-hourly or six-hourly. One study with 89 women (Pongsatha 2001) compared 50 mcg oral regimen four- or six-hourly whilst the other, with 133 women (Pongsatha 2002), compared 100 mcg given orally three- or six-hourly. There were no

differences in any of the outcomes studied when the data were combined, although there was significant heterogeneity in results for the outcomes of uterine hyperstimulation with FHR changes and oxytocin augmentation. In the study using 100 mcg, there was significantly less need for oxytocin augmentation when the misoprostol was given three- to four-hourly compared to when it was used six hourly (RR 0.72, 95% CI 0.54 to 0.96), Analysis 35.3.2.

(11) Oral misoprostol three-hourly versus oral misoprostol x two then routine oxytocin (analyses 37 and 38)

One study compared the use of oral misoprostol 25 mcg used three-hourly until in labour with a policy of two oral misoprostol doses (25 mcg) followed by routine oxytocin (De 2006). There were no statistically significant differences in any of the 10 outcomes.

(12) Oral misoprostol versus delayed vaginal prostaglandins (analysis 39)

Another small study of 61 women compared two policies for dealing with ruptured membranes at term (Shetty 2002a). One group had immediate oral misoprostol (50 mcg) whilst the other waited for 24 hours and then had vaginal prostaglandins (1 mg or 2 mg depending on Bishop Score). The only statistically significant outcome was in the 'vaginal birth not achieved in 24 hours' outcome, which was reduced in the immediate oral misoprostol group (RR 0.52, 95% CI 0.32 to 0.83), Analysis 39.1.

(13) Oral misoprostol versus dinoprostone vaginal insert (analysis 40)

One study compared the use of hourly titrated oral misoprostol with 10 mcg dinoprostone vaginal insert placed for a maximum of 24 hours (Rouzi 2014). There were no statistically significant differences in any of the 10 outcomes.

DISCUSSION

Efficacy compared to other induction agents

Oral misoprostol is more effective than placebo and equivalent to intravenous oxytocin, vaginal misoprostol and vaginal dinoprostone for the induction of labour in women. Oral misoprostol results in fewer caesarean sections than oxytocin alone. In the comparisons with oxytocin infusions, there seems to be a higher rate of meconium staining at all dosages, but this was not associated with any adverse effect on the fetus. It is possible that the meconium staining could be a direct effect of the misoprostol on the fetal gut. Gastrointestinal stimulation leading to diarrhoea is a well-described side effect of oral misoprostol in adults, and small amounts of misoprostol in the fetus could lead to the expulsion of meconium and hence meconium-stained liquor. This effect is also seen with vaginal misoprostol, but it appears to be smaller. This may be due to the lower peak serum concentrations that occur following vaginal administration.

There have been concerns in the past about uterine hyperstimulation with oral misoprostol. In studies where most women were given low dose oral misoprostol (20-25 mcg two-hourly), the hyperstimulation rates were the same as for vaginal dinoprostone (i.e. around 5% overall and 2.9% with fetal heart rate (FHR) abnormalities).

There were fewer studies comparing oral misoprostol and intracervical dinoprostone, but these found that the oral misoprostol (at doses of 50 and 200 mcg) resulted in stronger contractions than the dinoprostone. This led to higher rates of hyperstimulation and a more rapid labour, but with no effect on fetal outcomes.

Whilst no increase in adverse fetal outcomes was seen in these studies, this meta-analysis contains too few studies to exclude a difference in adverse outcomes which are rare (see additional Table 1 for numbers needed). However, the comparable safety data on vaginal dinoprostone are also limited. There are nearly 14,000 women in the trials in this review, which compares favourably with the Cochrane review of the current standard treatment vaginal dinoprostone (PGE2) with 10,000 women (Kelly 2009).

Should misoprostol be used orally or vaginally?

The large variety of doses of both oral and vaginal misoprostol used in the direct comparisons make it very difficult to interpret these data. The only consistent findings were a reduction in low Apgar score at five minutes in those given oral misoprostol (but there is no corresponding reduction in special baby care unit admission), lower rates of postpartum haemorrhage, and an increase in meconium-stained liquor. The cause of the improved Apgars in those given oral misoprostol is not clear, but it may relate to the hyperstimulation rates, which were generally lower in those given low-dose oral misoprostol. The relative acceptability of the oral and vaginal routes also need to be considered alongside this clinical data. Satisfaction was only considered in one study of 200 women (Colon 2005 (V25)), and in this study only two women (one in each group) expressed dissatisfaction. However, other clinical studies comparing oral and vaginal misoprostol have found increased satisfaction with the oral route.

In summary, there is some evidence that the oral route may result in improved clinical outcomes over the vaginal route. Given the likely greater acceptability for women using an oral route, it is the authors' opinion that the oral route should be preferred over the vaginal route.

What is the optimal dose of oral misoprostol?

The comparison with vaginal misoprostol is complicated by the wide variation in dosages used for both vaginal and oral misoprostol. Hence a comparison between 50 mcg oral misoprostol and 100 mcg vaginal misoprostol may give very different outcomes to a comparison between 200 mcg oral misoprostol and 25 mcg vaginal misoprostol. This is especially important given that both efficacy and side effects are a function of the ability of misoprostol to produce effective uterine contractions. The optimal dose will have to balance the desire for short induction to birth interval with impact of strong, effective uterine contractions on the fetal wellbeing and uterine muscle integrity.

An attempt to assess the effect of dose on effectiveness and safety has been made with the subgroup analyses by various doses of oral misoprostol. This has resulted in multiple subgroup analyses with a high potential for spurious results (type I error). To protect against this, we have analysed further the subgroups with significant heterogeneity within the results. We have used the interaction test (a form of chi-squared test) to assess the association with dosage. We chose uterine hyperstimulation without FHR changes as the outcome most closely representing a bioassay of misoprostol activity. The relative strength of various misoprostol dosages given

vaginally and orally is best seen in the graph for outcome 21.8, where similar hyperstimulation rates are seen when the dose of oral misoprostol is about double that of the vaginal doses. Similarly, the use of the same doses orally and vaginally results in generally lower hyperstimulation rates in the oral group. This suggests that equivalent biological activity is seen when the dose of oral misoprostol is about double that of the vaginal dose. Given that the Cochrane review of vaginal misoprostol suggests a dosage of 25 mcg vaginal misoprostol, it might be expected that the optimal dose (i.e. that which is equivalent to vaginal dinoprostone) would be 50 mcg. In the comparison with vaginal dinoprostone, most trials used oral misoprostol dosages of 20 to 25 mcg and it is the trials using this dose in which the CS rate may be decreased (Analysis 5.3, Analysis 6.3). Overall, therefore, the results of this review suggest that the optimal dosage of oral misoprostol is 20 to 25 mcg given two-hourly.

Obtaining a misoprostol dosage of 25 mcg tablets by cutting a 200 mcg tablet into eighths is difficult and imprecise. To get around this, the studies that used 20 to 25 mcg have generally dissolved the 200 mcg tablet in 200 mL water and administered 20 mL. Bioassays suggest that misoprostol remains active for at least 24 hours in this form (Matonhodze 2005). Whilst this will undoubtedly produce a more precise dose, there are ongoing issues around the storage of the unused solution. In view of the lack of good information about the stability of misoprostol in solution and the risks involved in having unused solution sitting around in containers on a labour ward, the best advice would be to discard any unused solution after administering each dose. The recent availability of misoprostol 25 mcg tablets is welcome and should overcome many of these problems.

Risks of induction

Some observational studies have reported a high uterine rupture rate when vaginal misoprostol was given to women who have had previous CSs. There is less evidence for oral misoprostol, but there were rupture rates of 10% (one of 10) and 9.7% (four of 41) in two studies that used oral misoprostol for induction (Aslan 2004; Gherman 2001a). Whilst the lack of ruptures in the 158 women in this review's randomised trials who underwent induction is encouraging (Carlan 2001 (V50); How 2001 (V25)), it would take a trial of over 60,000 women to evaluate whether there was an increase in the 0.5% background scar rupture rate in women undergoing a trial of vaginal birth (Table 1).

There is no consensus on what constitutes an acceptable risk of labour induction in the absence of life-threatening conditions for mother and baby. It is likely that most parents and clinicians would not be prepared to accept a 0.5% to 1% increase in serious adverse outcomes. In fact, it is likely that women would be prepared to spend more time on delivery suite if this means a safer labour, but there is a noticeable lack of data on this. Indeed, most studies in this review did not assess women's views or satisfaction rates.

Currently available data are nowhere near large enough to address the issue of safety of either the induction process (Table 1) ar the long-term follow-up of babies exposed to misoprostol. It is important to reiterate here that 'no evidence of difference' in this Cochrane review does not mean 'evidence of no difference'. In other words, when even more randomised data become available, small but important clinical differences between various regimens may become apparent, i.e. statistically significant.

Trials or meta-analyses that have adequate power to address the issue of rare adverse fetal outcomes will need to include an excess of 30,000 women. Until the logistics and financial resources are available to conduct such studies, alternative ways must be found of assessing the risk. Registries of women using oral misoprostol for induction may be a way of achieving this.

Summary of main results

In nine trials comparing oral misoprostol with placebo (1109 women, almost all with ruptured membranes), women using oral misoprostol were more likely to give birth vaginally within 24 hours (risk ratio (RR) 0.16, 95% confidence interval (CI) 0.05 to 0.49; one study in which all women received dinoprostone after 12 hours), needed less oxytocin (seven studies; 933 women) and had a lower CS rate (eight studies 1029 women).

Ten trials compared oral misoprostol with vaginal prostaglandin (dinoprostone) (3,240 women). There was little difference in the frequency of: vaginal birth within 24 hours (5 trials; 2,128 women), uterine hyperstimulation with fetal heart rate changes (7 trials; 2,352 women), and caesarean birth (10 trials; 3240 women), but evidence of slower inductions (cervix unfavourable/unchanged after 12-24 hours).

Five trials compared administration of oral with intracervical misoprostol (681 women). Oral misoprostol was associated with fewer instances of failure to achieve vaginal birth within 24 hours (3 trials; 452 women) but more frequent uterine hyperstimulation with fetal heart rate changes (3 trials; 490 women). The available data for these comparisons was however limited and the differences in caesarean birth were small (5 trials; 742 women).

Nine trials compared oral misoprostol with intravenous oxytocin (1282 women). There were no obvious differences in the frequency of: vaginal birth within 24 hours (6 trials; 789 women), or uterine hyperstimulation with fetal heart rate changes (7 trials; 947 women). There were, however, fewer caesarean births with oral misoprostol (RR 0.77, 95% CI 0.60 to 0.98; 9 trials; 1282 women). Oral misoprostol was associated with increased rates of meconium-stained liquor (seven trials; 1172 women).

Thirty-seven trials compared oral misoprostol with vaginal misoprostol (6417 women). There was little difference in the frequency of: vaginal birth within 24 hours (14 trials; 2,448 women), uterine hyperstimulation with fetal heart rate changes (29 trials; 5,503 women), and caesarean birth (35 trials; 6,326 women). However, there were fewer babies born with a low Apgar score in the oral misoprostol group (19 studies, 4009 women) and fewer women with postpartum haemorrhage (10 trials, 1478 women), but increases in meconium-stained liquor (24 studies, 3634 women).

Overall completeness and applicability of evidence

With 75 studies included in the review, there has been the opportunity to examine an extensive range of misoprostol regimens and comparisons with other induction methods. The studies have also been conducted in a wide range of settings, making the results applicable internationally. The studies have all however been conducted in settings where the participants can be closely monitored. This will reduce the risk to the baby of any uterine hyperstimulation, but means that the results may not be applicable to setting where fetal monitoring is not available. In those settings,

priority should be given to induction methods with low rates of hyperstimulation and/or fetal risks.

Quality of the evidence

There is adequate high-quality evidence within the 75 studies to make robust recommendations. There is however, a wide spread of oral misoprostol regimens examined in this review and a large variation in the quality of studies and reports. So whilst the quality of evidence for some comparisons is very robust (for example, oral misoprostol versus vaginal misoprostol), for other less common comparisons the strength of the recommendations must be lower (e.g. in those comparisons of different misoprostol regimens). With so many comparisons within the review, there is also a risk of statistical type 1 error, that is a false-positive result. The results in which there are very few studies, or heterogeneity, or those in which the meta-analysis result is of borderline statistical significance must therefore be treated with caution, and we have sought to do this.

Potential biases in the review process

Both review authors Z Alfirevic and AD Weeks have been involved in misoprostol research for many years, running some of the studies themselves and knowing many of the other people who have run other studies. There is therefore the potential to be biased in their assessment of the strength and importance of studies. The robustness of the methodology along with the peer review process will help to prevent any important effect on the results or recommendations of the review.

Agreements and disagreements with other studies or reviews

This review is one of several reviews within *The Cochrane Library* on induction techniques, but the only one that directly addresses the use of oral misoprostol. The World Health Organization, in preparation for their recommendations for the induction of labour, conducted an extensive review into all forms of induction of labour (WHO 2011). Their conclusion was that "oral misoprostol (25 mcg, two-hourly) is recommended for induction of labour" along with other methods including dinoprostone, vaginal misoprostol (25 mcg) and cervical balloon catheter. A review focusing specifically on low-dose oral misoprostol (20 to 25 mcg) was carried out using the Cochrane methodology by Kundodyiwa et al (Kundodyiwa 2009). The findings were similar to this review and the authors concluded that "low-dose oral misoprostol solution (20 mcg) administered every two hours seems at least as effective as both vaginal dinoprostone and vaginal misoprostol, with lower rates of caesarean birth and uterine hyperstimulation, respectively".

AUTHORS' CONCLUSIONS

Implications for practice

Oral misoprostol as an induction agent is effective at achieving vaginal birth. It is more effective than placebo, as effective as vaginal misoprostol and vaginal dinoprostone, and results in fewer caesarean sections than oxytocin alone. Oral misoprostol 20 to 50 mcg is as effective as vaginal misoprostol, and has lower rates of low Apgar scores and postpartum haemorrhage.

There had been concerns about high rates of hyperstimulation with oral misoprostol, despite the fact that this had never been shown to cause any increase in adverse fetal outcomes. With low doses of oral misoprostol, this does not appear to be a problem. Rates of hyperstimulation are equivalent to both placebo and the current gold standard, vaginal dinoprostone. Comparisons with vaginal misoprostol are made difficult by the wide variety of doses of both oral and vaginal misoprostol used, which results in significant heterogeneity.

Although there were no reported uterine ruptures in the 160 women in this review who were induced with misoprostol having had a previous caesarean sections, observational studies suggest that the uterine rupture rate is high with misoprostol, even when used in low doses. We therefore continue to recommend that it should not be used for women with previous caesarean section scars.

In deciding whether to change to oral misoprostol from dinoprostone, practitioners will need to balance the advantages of low-dose oral misoprostol (reduced caesarean section rate, low cost, heat stability and oral administration) against the problems resulting from the lack of a 25 mcg oral formulation (inaccuracies in dosage and the risks of making up the dosage oneself). If using oral misoprostol, the evidence suggests that the dose 20 to 25 mcg in solution and report serious adverse outcomes. Given that the primary consideration should be safety of induction, the evidence supports the use of oral regimens (using a maximum of 50 mcg) over vaginal regimens. This is especially important in situations where the risk of ascending infection is high and staffing levels mean that women undergoing induction cannot be intensely monitored (i.e. having one-to-one care and electronic fetal monitoring).

Implications for research

Methodologically sound clinical trials continue to be a priority, both in developing and industrialised countries. Ideally, these trials should be blinded and be limited to low-dose oral misoprostol (20 to 50 mcg). A randomised examination comparing different regimens would be helpful to determine whether the labour intensive one- to two-hourly administration is necessary, and the relative benefits of oral solution and the newly available 25 mcg tablets. Unblinded studies are prone to biased reporting of outcomes such as randomisation (induction) to birth interval, uterine hyperstimulation, fetal distress and maternal side effects. Also, in unblinded trials the threshold to perform caesarean section may vary according to the clinician's prior beliefs on the safety of misoprostol. On the other hand, administration of vaginal placebo may increase the number of vaginal examinations, influence clinical decision making and introduce bias in the assessment of women's and clinicians' views.

Any proposed dose regimen includes a trade-off between rapid birth and uterine hyperstimulation. Qualitative studies are required to assess how much emphasis women place on a short labour compared with increased perinatal risks that may be associated with shorter labours. Given that this trade-off may vary depending on personality and culture, a flexible approach to dosage may be appropriate.

Only large, pragmatic trials with adequate sample size or large registries will be able to address the risks of uterine hyperstimulation, uterine rupture, serious neonatal and maternal morbidity, and long-term safety. The contact author would be happy to collect the information on serious adverse outcomes associated with the use of oral misoprostol (maternal and perinatal

deaths, uterine rupture) and report them, with permission, in future updates of this review.

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